Mr. Christopher Hagan
Consultant Urologist
Belfast Health and Social Care Trust
Headquarters
51 Lisburn Road
Belfast
BT9 7AB

6 June 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. 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 11 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: Mr. Christopher Hagan
Consultant Urologist
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 27th June 2023.**

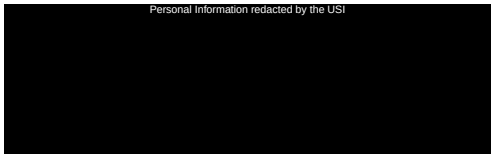
APPLICATION TO VARY OR REVOKE THE NOTICE

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 20th June 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 6th June 2023

Signed: 

Christine Smith QC

Chair of Urology Services Inquiry

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Section 21 - No 11 of 2023 Mr. Christopher Hagan

Date of Notice: 6th June 2023

Witness Statement of: Mr. Christopher Hagan

I, Chris Hagan, Consultant Urologist and Medical Director of the Belfast Health and Social Care Trust (Belfast Trust), will say as follows:

1. This is my first witness statement to the Urology Services Inquiry.

2. The documents that I refer to in this witness statement can be found in the exhibit bundle marked “CH1”.

3. I have been asked by the Urology Services Inquiry (USI) to address a number of questions set out in a section 21 notice dated 6 June 2023. I endeavour to address those questions in this witness statement. The USI has also provided me with a number of documents that bear on those questions. The section 21 notice and accompanying documents can be found behind Tab 1 in the exhibit bundle.

4. I am happy to try and assist the USI in any way I can. I have set out my recollections below to the best of my present ability. My specific direct experience of Mr O’Brien was over a 6 months period in excess of 20 years ago, and so I do not think that I now have a full and complete recollection of that period, simply due to the passage of time, but I have done my best to set out what I recall.

5. I also have to accept that, having reflected about my direct experiences of Mr O'Brien, I may see the events differently today. This is because I have myself had a further 20 years of experience, and because medical practice and clinical governance has continued to develop throughout that time. How we were trained and expected to deal with matters 20 years ago is very different from how someone would be trained and expected to deal with them today. There has been, and continues to be, significant cultural change in the medical profession, which I regard as a positive development. There is much work still to do.

6. Some of the other aspects of my statement relate to events that occurred in excess of 12 and 7 years ago. I have done my best to recollect those events as clearly as I can, but I have to accept that my memory is unlikely to be complete in respect of those matters either.

Current role and experience

7. I am presently 57 years old. I am a Consultant Urologist by profession. I am currently the Medical Director of the Belfast Trust. I have been in that role since January 2020. It is demanding and difficult.

8. I graduated from Manchester University Medical School in 1990 and following House Jobs in Manchester, began surgical training in Scotland in 1991. I decided to train in Urology and took a middle grade post in the Urology department of the Western General Hospital Glasgow from 1996 to 1998 where I was able to gain great experience in surgical urological oncology. The Urology unit in Glasgow was a large University Hospital teaching unit with 5 consultants and a good training reputation.

9. In August 1998, I returned to Northern Ireland as a higher surgical trainee on the Northern Ireland Urology training scheme. This was a 5-year rotational training program that, assuming satisfactory progress and the passing of the Fellowship of the Royal College of Surgeon, Urology (FRCS (Urol)) examination, would culminate in a Certification of Specialist Training (CCST) in Urology, entry onto the General Medical Council (GMC) specialist register for Urology and the ability to apply for a consultant post in Urology. There would have been approximately 4, 5 or 6 trainees on the

training scheme at any one time, but possibly at different stages of the 5 years of training.

10. From August 1998 to February 2000, I was based in the Urology Department in Belfast City Hospital. The Urology Department in Belfast is the regional Urology unit for Northern Ireland and at that time had 6 consultants. The first 6 months was doing general core urology, but the next year was in urological oncology where I gained extensive exposure to nephrectomy for kidney cancer, cystectomy for bladder cancer, retroperitoneal lymph node dissection for testis cancer, and early exposure to radical prostatectomy for prostate cancer. It was during this year that I decided I wanted to do oncological surgery.

11. Between February 2000 and August 2000, I was rotated to the Urology Department in Craigavon Area Hospital for 6 months as part of the Urology training rotation. At that time, I was a second year higher surgical trainee. This is when I first worked with Mr. O'Brien who, at that time, was an experienced Consultant Urologist. I speak further about this (rotational traineeship) later in this statement. There would have been higher surgical trainees in CAH before and after me, and on an ongoing basis, in line with the rotation plan of the training scheme.

12. In 2003 I was appointed a Consultant Urologist with special interest in Uro-oncology and Renal Transplantation in the Belfast Trust.

13. Between 2005 and 2009 I was the Clinical Lead for Urology Surgery in the Belfast Trust. I continued to perform complex surgery, but was also responsible for the local management and clinical governance of the Urology service in the Belfast Trust.

14. In 2009 I was appointed Clinical Director of Urology and Renal Services in the Belfast Trust. In 2010, following the 2009 Review of Urology (discussed below), the role evolved and I became Clinical Director for Urology in Belfast and South Eastern Trusts as part of what was known as "Team East". This lasted until 2013 when "Team East" was dissolved. Thereafter, I held the role of Clinical Director in Urology in Belfast Trust until 2015. I continued to perform complex surgery between 2009 and 2015, but was also responsible for the local management and clinical governance of the Urology

and Renal service in the Belfast Trust until 2010, and from 2010 a similar role across the Urology units of Team East until 2013, and then, following the dissolution of Team East, the Belfast Trust until 2015.

15. In 2015 I was appointed an Associate Medical Director within the Belfast Trust with responsibility for Children's, Maternity and Orthopaedic services. I undertook this role into 2016. I continued to perform complex surgery, but also had a senior management role and was responsible for the local management and clinical governance of the children's, maternity and orthopaedic services in the Belfast Trust.

16. In 2016 I was appointed Chair of Division for Children's Services within the Belfast Trust. I continued to perform complex surgery, but was also in a senior management role, responsible for the leadership, local management and clinical governance of the children's services in the Belfast Trust.

17. Between 2018 and 2020 I held the role of Deputy Medical Director for Risk and Governance within the Belfast Trust. I continued to perform complex surgery, but also had a senior management role with responsibility for risk and governance that included adverse incident reporting, complaints, coroners work and litigation, I was also responsible for standards and guidelines, emergency planning and Human Tissue Authority (HTA) licenses.

18. As indicated above, in January 2020 I was appointed Executive Medical Director of the Belfast Trust. This role has two main functions – a statutory role as Responsible Officer to around 1400 doctors, and as the lead for patient safety in the Belfast Trust, which is also a statutory function. In addition, I am also the professional medical lead for the Belfast Trust and have overall lead responsibility for integrated clinical governance, risk management, management of concerns in respect of doctors, appraisal and revalidation, undergraduate and postgraduate medical education, job planning, research and development, quality improvement, implementation of standards and guidelines. I also contribute to corporate planning, policy and strategic decision making within the Belfast Trust.

19. I should also say that during the last 10 years, during my time as deputy Medical Director and then Medical Director, the development of clinical governance in medicine, and in the Belfast Trust, has been considerable.

NOTE: As per email dated 06/09/2023 the highlighted date below should read 2000 and not 2010. Annotated by the Urology Services Inquiry.

My 2010 rotational training at Craigavon Area Hospital

20. The Urology Services Inquiry has asked me a specific question in relation to a conversation I had with Dr Colin Fitzpatrick of Practitioner Performance Advice (PPA) (formally the National Clinical Assessment Service or NCAS) about my time as a trainee in Craigavon Area Hospital (CAH) between February and August 2000 and my experience of Mr. O'Brien.

21. In my roles as Deputy Medical Director and then Medical Director in Belfast Trust, so from 2018 to 2021 (in 2021 Dr Fitzpatrick left his role with PPA), I would have spoken to Dr Fitzpatrick on a reasonably regular basis in his role as an NCAS advisor, and later as a PPA advisor. I would have sought his advice on the management of doctors for whom I was responsible in my roles in the Belfast Trust Medical Director's office.

22. Unfortunately, I do not recall the conversation Dr Fitzpatrick has referred to in his evidence to the USI (quoted in question 4 of the section 21 notice). If Dr Fitzpatrick recalls the conversation, then I have no doubt it occurred. However, I do not myself recall it, or when it occurred. However, I have tried to recall to the best of my ability my experience of working as a trainee in CAH with Mr. O'Brien in 2000.

23. As I indicated above, from February 2000 to August 2000, I rotated to the Urology Department in CAH for 6 months as part of the Urology training rotation. There would have been Specialist Registrar trainees in Urology on rotation at CAH both before and after my time there. At that time, I was in the second year of my five-year tenure as a Specialist Registrar, known as a higher surgical trainee. I had not worked in CAH before.

24. There were two consultants in the Urology unit in CAH, Mr. Aidan O'Brien and Mr. Michael Young. Whilst I had met both of them before at educational events, I had not worked with either of them previously.

25. The Urology department in CAH at that time had its own inpatient ward. I cannot remember precisely, but there were probably around 20 beds on the CAH Urology ward. The ward would have been fully staffed by nurses on a 24/7 rotation. At the time there would have been a ward sister and deputy ward sister for the Urology ward. The consultants were supported by a number of nurse specialists; nurses who specialised in Urology, having had additional urology training.

26. I was the only Urology Specialist Register in CAH during my rotation, but there were a number of other junior grade medical staff (Senior House Officers and Junior House Officers) also there at the time. Like specialist registrars, they will also have changed over time on rotation. My recollection is that the CAH Urology unit was busy with good training opportunities.

27. Whilst Mr. O'Brien and Mr. Young had their own sets of urology patients, they did do a joint Thursday morning ward round together. I attended this. It meant they were involved with each other's patients. They would also have covered for each other, seeing each other's ward patients, on the weekend rotations and for holidays.

28. I have reflected over time, arising from the questions posed by the USI in the section 21 notice, about the 6 months I spent in CAH. As I have done so, I have recalled that there were a number of situations that arose that caused me to feel concerned about some of the practices of Mr. O'Brien. With the passage of time it is not now possible for me to recall all the details. I did not keep a formal record at the time. I am afraid it would not have occurred to me to do so. I did raise issues that concerned me with Mr. O'Brien himself, and also with Mr. Young about Mr. O'Brien, during my 6 months rotation. In 2000 that would have seemed like a brave or courageous step from a higher surgical trainee. I am sure I probably saw it that way at the time. Whereas, with all the more recent and ongoing changes in medical culture (transparency, openness, and the many mechanisms for raising concerns) and the development of clinical governance (introduced into health and social care around 2003), it hardly seems

sufficient by today's standards when the opportunity for trainees to raise concerns are much more organised and available, and their use encouraged. Trainees are now heard and listened to in a way they would not have been in 2000.

29. As I have reflected on my time in CAH for the purposes of providing this statement it is possible to broadly identify 9 areas of concern that I address below. I would not have counted them up at the time in order to regrade them as some form of accumulation, and would not have had the "slow time" thinking about them facilitated by the questions posed by the USI. It is difficult for me to say whether the concerns I now identify, as I reflect back with hindsight, and with awareness of investigations into Mr. O'Brien, were concerns considered by me to be of the extent and nature that I now see them, and I would ask the USI to bear that in mind. It is also the case that how I responded to the matters that concerned me in 2000 would be different from how I would respond to them today, if I were still a trainee, including because the available mechanisms for responding are significantly different.

30. I should also say at the outset that I recognise and acknowledge that Mr. O'Brien was someone, in 2000, who was a senior consultant. He appeared popular with patients, pleasant to staff, and someone who worked hard (including into the evenings). I also acknowledge him assisting me to secure the opportunity to focus on a particular specialism I was interested in when training in Dublin in 2021.

31. The concerns were as follows:

I. **Patients being admitted to the ward for prolonged intravenous fluids and antibiotic therapy.** There was a group of patients that seemed to me to be being regularly admitted to the ward for antibiotics and IV fluids by Mr. O'Brien. My recollection is that these patients would make contact with Mr. O'Brien in some way and be admitted directly to the ward as an inpatient for treatment. When I asked about this practice the ward nurses referred to this treatment as "*Mr. O'Brien's regime*". I would do an unaccompanied ward round every morning during my 6 months rotation when I would come across these patients. It was often not clear to me the reason for this approach, or the evidence base for the treatment. I considered patients who fell into this category could have been managed as

outpatients, as they could eat and drink. I did not encounter this approach in any other urological unit I worked in before or since.

II. **Cystectomy and Orthotopic neobladder formation.** Amongst the patients coming in for antibiotic therapy and IV fluids was a patient who had had a cystectomy (a major operation to remove the bladder that would generally take between 4 and 5 hours) and neobladder (creation of a new bladder) to treat recurrent urinary tract infections (UTIs). There was a young woman, in her early 20s, who had this procedure before I arrived to do my rotation at CAH, but who then had subsequent admissions for fluids and antibiotics during the time I was in CAH. I am not absolutely certain of the correct name of the patient at this remove, but my legal representative will provide the USI with the name that is in in my memory. The USI may wish to look at the particular case. The young woman made a lasting impression on me as she was really miserable, especially as she was continuing to have UTIs notwithstanding the major operation she had been put through. The predominant indication for cystectomy and neobladder is for treatment of bladder cancer and I was disturbed that this major procedure had been undertaken for recurrent UTIs in a young woman. I could find no evidence base in the literature for this. At the end of a ward round, where I had accompanied Mr. O'Brien, I challenged him as to why he had carried out such a radical and life changing operation on this young woman in the context of recurrent UTIs. He remarked that someone else had said that to him, and he justified it to me by telling me he had specifically discussed this case with a Urologist in the United States of America (USA) who agreed it had been a reasonable course of action. I felt, as a second-year surgical trainee, inevitably anxious about challenging an experienced consultant, that I had expressed my view and Mr. O'Brien had provided an explanation that was hard to dispute at the time. I think this was the only case of this type that I myself saw during my rotation, but I cannot say if there were others with whom this approach was taken. I did speak to Mr. Young during my rotation about various concerns I had about Mr. O'Brien, but I cannot now say whether this was one of the matters that I spoke to Mr. Young about. I may have, but I cannot say that I did. Looking back on this now, with 17 years' experience as a Consultant Urological Cancer Surgeon, I can see no justification for the operation.

III. **Trans Urethral Resection of the Prostate procedures (TURP).** TURP is a core urological procedure for the treatment of benign prostatic hypertrophy, to remove symptoms of bladder outlet obstruction. In 2000, it was performed using monopolar diathermy (a form of electric current) to resect (cut and remove) tissue from the prostate via an endoscopic sheath. Glycine (a potent neurotoxin) 1.5% fluid was used as a non-ionic irrigation fluid in order to maintain vision during the procedure. TURP is generally a safe procedure but carries risks including bleeding requiring transfusion, incontinence, impotence, sepsis and a rare but life threating condition called TUR syndrome. TUR syndrome is caused by absorption of Glycine fluid, leading to Glycine related side effects in the Central Nervous System (CNS), increased plasma ammonia levels and dilatational hyponatraemia. This can lead to serious cardiac, neurological and respiratory side effects and even occasionally death. The key risk factors for TUR syndrome include resection time (greater than 1 hour), height of the fluid bag (greater than 70cm) and large blood loss. TURP is a key surgical procedure for trainees to gain competency. At the time of completing my training in urology, trainees were expected to have completed at least 100 TURPs. Consequently, I would have undertaken most of the TURPs at CAH during my 6 months rotation, which was generally one or two a week. One of the key mantras of the training which I experienced in Glasgow, Belfast, and later Dublin (where I also worked during my 5 years as a surgical trainee) was that resection must stop no later than an hour, and ideally cease by around 50 minutes (to allow for another 10 minutes to control any bleeding). I was therefore disturbed as a trainee in CAH when a TURP that Mr. O'Brien was carrying out involved a resection that lasted significantly greater than 1 hour. The case I recall involved resection time approaching 2 hours, and the anaesthetist and nursing staff expressing concerns to Mr. O'Brien about the length of operating time, but Mr. O'Brien continued. I thought this was a patient safety issue because it was putting the patient at what I considered to be unnecessary risk. I expressed that view to Mr. O'Brien. Mr. O'Brien's view, as far as I recall it, was that resection time was not the significant issue I considered it to be. I believe I did speak to Mr. Young about this issue (I did speak to him a number of times during my rotation about different issues) and my recollection is of him saying "that's just Aidan". I cannot

say for certain that the remark from Mr. Young that I recall was definitely in connection with this issue, but it is definitely a phrase that Mr. Young used to me when I raised an issue about Mr. O'Brien during my time in CAH.

IV. **Ureteric Stone treatment.** There were two different issues in this area. (1) First, emergency admission to urology units for stones in the ureter (the tube connecting the kidney to the bladder) is common. Most stones are less than 1cm in size and around 90% should pass spontaneously without surgical intervention. There was emerging evidence in and around 2000 that prescribing Alpha-blocking medication, such as tamsulosin, could assist stone passage. This conservative management of stones was my experience from working in Glasgow and Belfast. Mr. O'Brien's approach to ureteric stone management was very different and his preference was to intervene surgically at a very early stage. When discussing patient management with Mr. O'Brien, I challenged him in relation to this approach, as I felt that suitable stones should be allowed to pass naturally. This is because intervention carries risks, including sepsis and ureteric perforation. Mr. O'Brien however referred to his training in Tallaght Hospital in Dublin, and that this was how he managed stones. Generally, I found Mr. O'Brien to be dismissive of me when I raised concerns. He was clear that it was an appropriate course of treatment. (2) The second issue related to the energy source used in the destruction of stones. Destruction of ureteric stones requires an energy source. In 2000, there were a number of sources commonly used when operating on the ureter, such as laser and pneumatic devices (such as the swiss lithoclast). Both these types of energy sources had good safety profiles. Mr. O'Brien's preference however was to use an electrohydraulic (EHL) energy source. It was powerful and unpredictable. EHL has uses for large bladder stones and kidney stones, where its use is safe, but, in the ureter, it carries a very high risk of ureteric perforation. I discussed this risk with Mr. O'Brien, as I felt this was a high-risk energy source to use in the ureter, with real safety risks. I described my experience with the lithoclast, which has a zero risk of ureteric perforation, and questioned why he would not use it, as it was very cheap technology. Again, I found Mr. O'Brien to be dismissive of my concerns. Mr. O'Brien did not accept my view. Unfortunately, when carrying out a left ureteric stone case, with Mr. O'Brien directly supervising

me, he told me to use the EHL probe to break up the stone. As instructed, I did this and the discharge of the energy source caused a very large perforation in the upper third of the ureter. Mr. O'Brien took over the case and was unable to negotiate a ureteric stent into the kidney due to the size of the defect. This then required the patient to have an open surgical repair of his ureter. I was very distressed by this complication, as I felt very much to blame for it, even though I had carried out the instructions of the supervising Consultant. Mr. O'Brien spoke to the patient afterwards, as he was ultimately responsible for the operation. I was not present. I don't know what Mr. O'Brien said to the patient. With hindsight, it is clear to me that the direction I received from the supervising Consultant, to use the EHL, was not appropriate in the situation and that this was an entirely avoidable complication.

V. **Paediatric Urology.** I recall, during my rotation, Mr. O'Brien expressing the view that Craigavon District General Hospital (DGH) Urology unit should be able to carry out the majority of urological procedures, including paediatric urologic procedures. There is nothing necessarily wrong with that view per se, but sub-specialisation in urology was becoming very common and for many years paediatric urology had generally been performed by paediatric trained urologists working in paediatric units. In Northern Ireland, there is a paediatric urology team in the Royal Belfast Hospital for Sick Children (RBHSC). At that time in urology, around 2000, it was generally accepted that minor procedures such as testicular torsion and circumcision in children could be safely performed in DGHs, but more complex procedures should be performed in specialist centres, such as RBHSC. Mr. O'Brien however had acquired a set of paediatric cystoscopes. I thought this was very unusual as there are very few indications for cystoscopy in a child, and usually it will be in children with congenital conditions or vesico-ureteric reflux (both of which would be managed in tertiary specialist centres). I did not see Mr. O'Brien ever perform a cystoscopy in a child, and cannot say if he ever did. I can recall one case of a child who had nocturnal eneuresis. Mr. O'Brien and I disagreed over the management of the child's condition. Standard treatment then was the use of desmospray or desmotabs, as this condition usually settled with age. There is often no need for investigations, other than perhaps an ultrasound of the kidneys and

bladder, unless there are unusual daytime features. Mr. O'Brien was of the view that the child required invasive tests such as urodynamics (which requires a general anaesthetic and catheters). In my view at the time this was over-investigating and unnecessary, as the course of treatment would be expected to be the same in any event. I cannot say whether Mr. O'Brien did in fact carry out the invasive tests, I just remember disagreeing with him when he thought this should be the course undertaken.

VI. **Radical Prostatectomy and high PSA.** During my 6 months in Craigavon Area Hospital, Mr. O'Brien performed operations in a small number of pelvic cancer cases, such as radical cystectomy for bladder cancer and radical prostatectomy ("**RRP**") for prostate cancer. His patient selection for RRP differed to what was generally accepted by UK urologists at that time, though I accept there would be some support beyond the UK for the approach Mr. O'Brien advocated. This was at a time before MRI scans were routinely used to assess suitability for surgery. Generally, men with a Prostate Specific Antigen (PSA) test score of less than 10 and no higher than 15, with confirmed prostate cancer, were thought suitable for RRP, as higher PSAs tended to be associated with higher risk of lymph node positive disease or extracapsular disease and were best treated with radical radiotherapy and hormone treatment. Mr. O'Brien however offered RRP to men with very high PSAs and would commence them on hormone treatment prior to surgery to reduce their PSA score. It is likely that men with a high PSA will have micro-metastatic disease. Commencing hormone treatment pre-surgery will lower the PSA before surgery but does not cure metastatic disease and so surgery provides no ultimate benefit. I disagreed with Mr. O'Brien about his approach and argued that the path he was taking may also in fact lead to earlier hormone resistance in the patients, as these men would then not be hormone naïve when they developed symptomatic metastatic disease. Mr. O'Brien did not share my view. My recollection is that Mr. O'Brien did openly disagree with others in the region on the issue of the treatment of prostate cancer.

VII. **Priapism and penile disassembly.** In my last week as a trainee in CAH in 2000, a patient was admitted with a long-standing priapism (an erection of the penis that

does not go away). Once a priapism has been established for more than 24 to 48 hours, surgical decompression or haematoma evacuation will not be successful as the haematoma will have organised and erectile function will be lost. Andrologists (physicians who specialise in treating men's reproductive-related issues) in Great Britain were recommending early referral to London for insertion of artificial penile prosthesis for management of this rare condition. However, in the case I remember, Mr. O'Brien took the patient to theatre and performed what I can only describe as a penile disassembly by separating the corporal cavernosum and spongiosum tissues. I was not myself "scrubbed" in for the procedure along with Mr. O'Brien, and whoever was assisting him, but I just remember being present in the theatre at some point and wondering what Mr. O'Brien was trying to achieve. I remember being concerned that the procedure could risk compromising the vascular supply to the penis. I remember leaving the theatre as I did not want to watch what was happening. I never found a description of the procedure in any text. My recollection is that when the patient returned to the ward there was concern in respect of ischaemia of parts of the penis. I do not know the final outcome for this patient as I left CAH to return to BCH as part of the urology rotation. This patient will have been on the Urology ward for a period of time post his operation, so it may well be Mr. Young or others will recall the case because of its unusual features.

VIII. **Out-patient practice.** Mr. O'Brien's outpatient clinics were busy with large numbers of patients. I assisted with those clinics during my rotation. As a trainee, I generally saw review patients and Mr. O'Brien tended to see new patients. I remember coming across review patients who were on repeat follow up appointments with no clear rationale for this, at least not that I could see. I would therefore try and discharge as many patients as I could to improve clinic efficiency. I recall one specific patient who I discharged from clinic in Banbridge for this reason, but who was then back at the clinic the following month. His symptoms had not deteriorated or changed and I asked him how he had been re-appointed. The patient told me that he had phoned Mr. O'Brien's wife (who I believe assisted Mr. O'Brien with his private patients) who arranged (presumably with the clinic's appointment secretary) for him to be re-instated on the clinic. I was very surprised

that this had happened but was concerned that perhaps something would be said to me for having discharged the patient in the first place. Mr. O'Brien never mentioned it to me. As I reflect on this now for the purposes of this statement, I realise that was an unusual practice that was occurring.

IX. **Administration delays.** As I reflect on Mr. O'Brien's administrative processes, having subsequently had many years in practice myself, it would be fair to say that I look back on Mr. O'Brien's administrative processes as appearing disorganised and chaotic. I accept it may have been a symptom of his workload, but his office was always full of patient charts awaiting dictation which, as I recall, often took a considerable time to process. His secretary would complain about it. The delays were probably compounded by what I now, with hindsight, consider to be his tendency to over investigate patients. However, he also wrote what seemed to me to be extremely long letters, which often seemed to struggle to get to the point. This will have added to the turnaround time. It is of course easy to criticise the practice of others, but it is obviously important, when writing letters to GPs, that they are timely, and that the diagnosis and management plan is succinct and clear.

Raising concerns as a trainee

32. As I have indicated earlier in this statement, I did raise issues with Mr. O'Brien about his practice during my time as a surgical trainee in Craigavon Area Hospital. Mr. O'Brien did not agree with me and was essentially dismissive. I did also raise issues about Mr. O'Brien with his Consultant colleague, Mr. Young, during my rotation. This would have been in an informal manner, and I would not have recorded them in written form. It just would not have occurred to me at the time to do that. It means that I cannot now say precisely what I raised with Mr. Young, or how I precisely I said it. My recollection was that Mr. Young's response to what I said was "that's just Aidan". Mr. Young did not give me the impression that he had any major concerns about the matters I was raising. I don't know if Mr. Young spoke to Mr. O'Brien about any of them, or if Mr. Young spoke to anyone else about them. I certainly thought at the time that I was brave in speaking to both the consultant himself, and to his consultant colleague. In my experience, it certainly was very unusual for trainees in 2000 to raise concerns about consultants and their practice. There were a number of reasons for

this, including the undeniable fact that the trainee is generally much less experienced than the consultant, and therefore the trainee may just be wrong (no matter how much they think they are right). There is also inevitably a fear of adverse consequence for the trainee, such as not obtaining a consultant post in the region, and/or being talked about by senior colleagues as someone who did not know what they were talking about. Both of these could have career consequences, and potentially justifiably so (if you were in fact wrong). At the time I dealt with my concerns in the way I understood I should do so, which was to speak to another senior consultant. This was because they would be best placed to know whether the issues I was concerned about were in fact something to actually be concerned about. In 2000 I did not regard my role as a trainee as involving escalating my concerns beyond Mr. Young.

Review of Adult Urology Services in Northern Ireland (2009)

33. The USI has asked me, at questions 5 and 6, about any further capability concerns I had about Mr. O'Brien, and about a 2016 case that appears to have been explored in 2021 as part of an SAI process. I will endeavour to address those matters in the remainder of this statement. There were issues that arose in late 2010 over the centralisation of urology cancer treatment, then the issues in 2016, and an issue that I recall from sometime between 2017 and 2019. I will deal with each in turn. I should say that, in respect of each of these matters, I was an employee of the Belfast Trust, and within its governance structure. I was not involved with the Southern Health and Social Care Trust or Craigavon Area Hospital.

34. The context to the 2010 issue arose from the outworking of the March 2009 "Review of Adult Urology Services in Northern Ireland" (the Urology Review). The Urology Review had been commissioned by the then Minister for Health. It had a multi-disciplinary and multi-organisational steering group. It also had an external advisor in the form of Mark Fordham, a Consultant Urologist from Great Britain. A copy of the Urology Review can be found behind Tab 2 in the exhibit bundle.

35. The background to the review is important. There was a need to better organise urological services in Northern Ireland to best meet the needs of the population by coordinating how urological units in the region worked more collaboratively together.

In particular, there was an urgent need to better organise how radical urological pelvic cancer surgery for prostate cancer (radical prostatectomy) and muscle invasive bladder cancer (radical cystectomy) was delivered.

36. In 2002, the National Institute for Health and Care Excellence (NICE) had issued guidance entitled "Improving Outcomes in Urological Cancers" (IOG). A copy can be found behind Tab 3 in the exhibit bundle. Key recommendations included the following (see internal page 6):

"All patients with Urological cancers should be managed by multidisciplinary Urological cancer teams. These teams should function in the context of dedicated specialist services, with working arrangements and protocols agreed throughout each cancer network. Patients should be specifically assured of:

- *Streamlined services, designed to minimise delays;*
- *Balanced information about management options for their condition;*
- *Improved management for progressive and recurrent disease.*
- *Members of Urological cancer teams should have specialised skills appropriate for their roles at each level of the service. Within each network, multidisciplinary teams should be formed in local hospitals (cancer units); at cancer centres, with the possibility in larger networks of additional specialist teams serving populations of at least one million; and at supra-network level to provide specialist management for some male genital cancers.*
- *Radical surgery for prostate and bladder cancer should be provided by teams typically serving populations of one million or more and carrying out a cumulative total of at least 50 such operations per annum. Whilst these teams are being established, surgeons carrying out small numbers*

(five or fewer per annum) of either operation should make arrangements within their network to pass this work on to more specialist colleagues."

37. As set out in the Urology Review, in Northern Ireland in 2007/08, 77% of radical pelvic operations were undertaken in Belfast Trust at Belfast City Hospital (BCH). Neither the Southern Health and Social Care Trust or Western Health and Social Care Trust (separately or together) undertook the required number (50) of such operations. Four of the existing Urology Consultants in Northern Ireland undertook small (less than 5) numbers of each of the procedures. So how we were operating in Northern Ireland was not in accordance with the IOG. With a total of just over 100 procedures a year, and a population of less than 2 million, a single site for radical pelvic surgery in Northern Ireland was considered by the Urology Review to be the appropriate way forward for IOG compliance to be achieved.

38. When the review of Urology Review reported in March 2009 it made two recommendations in respect of pelvic cancer surgery (see internal pages 6 and 7, and 36 to 39):

- ***Recommendation 19****: By March 2010, at the latest, all radical pelvic surgery should be undertaken on a single site, in BCH, by a specialist team of surgeons. The transfer of this work should be phased to enable BCH to appoint appropriate staff and ensure infrastructure and systems are in place. A phased implementation plan should be agreed with all parties.*

- ***Recommendation 20****: Trusts should ensure that surgeons carrying out small numbers (<5 per annum) of either radical pelvic operation, make arrangements to pass this work on to more specialised colleagues, as soon as is practicably possible (whilst a single site service is being established).*

39. The 2010 issue I describe below included delays in CAH patients with complex pelvic (urological) cancer cases being transferred to BCH. I have asked my legal representative to provide the USI with the emails and documents that I have found to date that bear on this issue. I have not at present exhibited the material to the witness

statement in view of the amount of redaction the material may require. My email of 28 September 2010 at 15.25 to the then Medical Director and Associate Medical Directors of the Belfast Trust perhaps usefully summarises the issue that concerned me.

40. On Friday 17 September 2010, Heather Trouton, then Acting Assistant Director of Acute Services in CAH, contacted Beth Molloy, of HSCB, and Diane Corrigan, a PHA Commissioner, about two patients in the Southern Health and Social Care Trust (Southern Trust) on whom Mr O'Brien was planning to perform cystectomies. The PHA's Diane Corrigan instructed that these patients should be referred to Belfast for surgery.

41. Further correspondence on 21 September 2010 between the Belfast Trust and the Southern Trust indicated that there were in fact five patients listed in Southern Trust for pelvic cancer surgery – three requiring cystectomy and two requiring radical prostatectomy. Those cases all needed to be transferred to BCH.

42. During an email exchange, with those involved in the discussions that took place I said, amongst other things, the below to Dianne Corrigan at the PHA on 22 September 2010:

> *"…We have accommodated onto theatre lists in BCH these complex pelvic cancer cases that should be done here to meet IOG guidance. This was done at very short notice with little or no warning and in a very unusual fashion. These patients should have been referred some time ago via the appropriate MDT and it would have been much easier to accommodate them."*

43. The patients were then discussed at the regional Multi-Disciplinary Meeting (MDM) on 23 September 2010. Two were not deemed suitable for radical surgery. Of the five patients referred, I personally saw three requiring cystectomy. In view of the questions asked of me by the USI, I consider I am obliged to draw the three cases, and correspondence Mr O'Brien sent relating to them, to the attention of the USI. I have

asked my legal representative to provide to the USI the details of the three patients I saw so that the USI can consider their cases. I provide a very brief summary below to try to illustrate the issues (the references to Patients 1, 2 and 3, and the text in square brackets are my attempts to ensure anonymity for the patients concerned):

Patient 1

I. Patient 1 was referred to CAH by a GP in June 2010 with haematuria. They underwent TURBT in July 2010 in CAH; histology sarcomatoid bladder cancer with CT scan demonstrating no metastatic disease. The presence of high grade aggressive sarcomatoid bladder cancer should have triggered immediate discussion about cystectomy irrespective of there being no detrusor muscle in the specimen. However, the patient underwent another TURBT in August 2010 which confirmed the same pathology. The patient also had a bone scan in August 2010 which was also negative (bone scan is not a recommended investigation for bladder cancer). The patient was then readmitted to CAH in September 2010 and had another CT scan which demonstrated regrowth of the tumour at which point a decision was made to proceed with cystectomy in Craigavon at the end of September 2010. In Mr O'Brien's letter to the GP he wrote:

> *"As you are now aware, a decision was made by officials in the Department of Health, in conjunction with the Commissioner, to cancel [Patient 1] admission and to have his further management transferred to Mr Hagan, Consultant Urologist at Belfast City Hospital, and with whom I gather that an appointment has been arranged for [date] September 2010. [Patient 1] and [their] family have been gravely distressed by the cancellation of [their] admission. [Patient 1] is suffering gravely from severe lower urinary tract symptoms. I do hope that [their] further management can be expedited as soon as is possible."*

Mr O'Brien further wrote to the patient:

"*Dear [Patient 1]*

I write to express my deepest regret that I was not permitted to proceed with your admission to Craigavon Area Hospital on [date] September 2010 as had been planned. I entirely acknowledge your continued suffering and the urgency with which you deserved to have your suffering relieved. I also entirely acknowledge the additional distress that the cancellation has inflicted. I do hope that your management under the care of Mr Hagan, Consultant Urologist at Belfast City Hospital, will take place as soon as is possible."

I assessed the patient on 27 September 2010 following discussion at the regional Multi-Disciplinary Meeting (MDM) and admitted the patient to BCH that day for surgery. The surgery was to take place the following week. Surgery was uneventful and the patient is alive today. It must be noted however that there was an unnecessary re-resection of the tumour in CAH and unnecessary investigations which delayed definitive treatment.

Patient 2

II. Patient 2 was admitted to CAH in July 2010 and had TURBT, pathology of which demonstrated muscle invasive bladder cancer obstructing the right kidney. CT demonstrated extensive lymphadenopathy – inguinal, iliac, para-aortic and mesenteric that would suggest metastatic disease. The patient was then scheduled for another cystoscopy at the end of August 2010. It is not clear what the rationale was for that. The patient also underwent a bone scan, the reason for which is unclear. Mr O'Brien wrote to the patient's GP at the end of September 2010:

"I had intended to proceed with [Patient 2] admission to our department on [date] October 2010 for right nephroureterectomy,

radical cystectomy and ileal conduit urinary diversion. However a decision has been made by officials in the Department of Health, that [Patient 2] would not be permitted to undergo surgery at Craigavon Area Hospital and that he would be referred instead to Mr Hagan, Consultant Urologist at Belfast City Hospital, for further management. I gather that an outpatient consultation has been arranged with Mr Hagan on [date] September 2010."

Mr O'Brien further wrote to the patient:

"Dear [Patient 2]

I write to express my profound regret that you have not been permitted to have your surgery at Craigavon Area Hospital. I gather that an appointment has been arranged for you with Mr Hagan, Consultant Urologist at Belfast City Hospital, on [date] September 2010. I do hope that all will go well with your future management there.

I arranged for the patient's imaging and pathology to be discussed at the uro-oncology regional MDM towards the end of September 2010 when the consensus was of likely metastatic disease due to the volume of lymphadenopathy. In this situation, of likely metastatic disease, chemotherapy was recommended as initial treatment rather than surgery. If the response to chemotherapy was good, then surgery or radiotherapy could be considered depending on symptoms. However, it is important to state that metastatic bladder cancer is not curable and therefore the role of radical surgery is limited. I met the patient towards the end of September 2010 and explained this to them, referring them for ongoing care to oncology. The patient was not aware prior to me seeing them that they had in all likelihood metastatic disease which would not have been curable with surgery. Unfortunately, they had a poor response to chemotherapy and the disease progressed. They sadly died in 2011.

Patient 3

III. Patient 3 was admitted to CAH in August 2020 for TURBT. There was a background history of neuropathic bladder. Histology confirmed poorly differentiated muscle invasive bladder cancer with squamous differentiation. CT scan demonstrated multiple pulmonary nodules which the radiologist felt represented pulmonary metastatic disease in the context of the bladder findings. The patient was symptomatic from their bladder cancer and Mr O'Brien's preference for treatment was cystectomy followed by adjuvant chemotherapy. Although Mr O'Brien made the patient aware of the metastatic disease, it was not clear if it had been explained that this was incurable. Mr O'Brien referred the patient for an oncology opinion and wrote to the GP in September 2010:

> *"Further to my letter of [date] September 2010, I write to confirm that [Patient 3] did have a consultation with Dr McAleese on [date] September 2010. I am sure that we will both receive a formal communication from Dr McAleese in due course. However I have been able to read his handwritten notes. I would agree that palliative radiotherapy to [their] bladder would be entirely less effective than cystectomy and would have the additional significant risk of enteric toxicity due to a loop of bowel, which surrounds the dome of [their] bladder, as seen on CT scanning. Whilst it would appear that Dr McAleese had some concerns that palliative cystectomy was not a standard treatment, in this clinical pathological situation I gathered that he believed that it was not entirely inappropriate. He felt that chemotherapy prior to surgery would be hazardous. He found [Patient 3] to be fatigued, for which reason he prescribed Dexamethasone, 4mg daily, and I believe that he has arranged to review [them] on [date] October 2010.*
>
> *I had intended to proceed with surgery on [date] October 2010. However, most regrettably, a decision was made by officials in the Department of Health that [Patient 3] would not be permitted*

to have [their] surgery at Craigavon Area Hospital, but instead that [they] would be referred to Mr Hagan, Consultant Urologist at Belfast City Hospital, and with whom I believe an appointment has been arranged for [date] September 2010. [Patient 3] was advised of this decision on [date] September 2010. When I contacted [them] by telephone subsequently, I found [them] to be most distressed by this decision. I gathered from [them that [their] greatest fear was that Mr Hagan would not agree to [them] having a cystectomy performed.

I advised [Patient 3] that we had reviewed [their] case at our multi-disciplinary meeting on [date] September 2010, and when it was agreed by my colleagues here that the optimal form of management would be cystectomy and ileal conduit urinary diversion, followed by adjuvant chemotherapy, and for all of the reasons previously detailed."

Mr O'Brien also wrote to me on the same day:

"I enclose recent correspondence pertaining to this [age] [Patient 3], who has muscle-invasive, poorly differentiated, transitional cell carcinoma of [their] urinary bladder, and which has undergone squamoid differentiation, and which is associated with several, small volume, bilateral pulmonary lesions, and which are probably metastatic. [They are] particularly keen to proceed with cystectomy and ileal conduit urinary diversion as soon as is possible, as [their] bladder is particularly troublesome, even though [they have] an indwelling urethral catheter, and so that [they] may proceed with adjuvant chemotherapy thereafter.

I do believe that it is important to advise you that [Patient 3] has been [personal circumstances] for some years. [They have a

Personal Information redacted by the USI

[They] lives alone, though does have the support of friends. [They]

would have much preferred to have [their] surgery here at Craigavon Area Hospital and will find the prospect of surgery at Belfast City Hospital all the more detached from [their] tenuous support base. However, even more importantly, [their] present dread is that you would not agree to proceed with cystectomy. I do hope that you will agree to do so. I dread to think of the distress, if you were not to agree."

This assessment contrasted with the CAH MDM discussion at the end of September 2010. Dr McAleese had seen the patient by the date of the MDM in September 2010, commenced Patient 3 on steroids and deemed them unfit for any treatment at that stage. Dr McAleese had planned to review Patient 3 in two weeks.

I also met the patient at the end of September 2010 to discuss their treatment options. Their bladder symptoms were better controlled but unfortunately they had lost a considerable amount of weight, suggestive of systemic metastatic disease. At the meeting with the patient, I explained that the unanimous decision of the regional MDM, given the presence of quite extensive pulmonary metastatic disease, was that palliative chemotherapy was the best option and I explained that unfortunately their bladder cancer was not curable.

Unfortunately, the patient's bladder cancer progressed rapidly and they died in the early part of 2011. Given their poor performance status in the context of metastatic bladder cancer it was my view, supported by the regional MDM, that cystectomy was not appropriate. This is a very major operation that takes many months to recover from and by subjecting a patient to this in the last months of life with no benefit (and likely detriment) I considered to be poor judgement. I have worked as a cystectomy surgeon for 17 years in the regional unit and saw very few patients who may have benefited from palliative cystectomy. In patients in this situation, with intractable urinary symptoms, often a catheter or

cutaneous ureterostomy combined with palliative radiotherapy provided good palliation in the last months of life without resorting to futile major surgery.

44. Following my meeting with these 3 patients, I was very concerned about the care they had received in CAH, and in particular the delay in one patient with aggressive bladder cancer receiving definitive treatment that may have affected their outcome (Patient 1), and the decision-making to perform cystectomy in patients with incurable metastatic bladder cancer (Patients 2 and 3). These were examples of the reason for the IOG Guidance and why the Urology Review, in order to comply with the IOG Guidance, had recommended in March 2009 that patients requiring radical pelvic cancer surgery should be centralised in Belfast by March 2010. This was to ensure that they received optimal care from a high-volume multidisciplinary team.

45. I believe my email of 28 September 2020, in the aftermath of seeing these three patients, to the then Belfast Trust Medical Director and the then Associate Medical Director made my concerns clear. This was the appropriate route for me to escalate the concerns that I had. The length and tone of my email is probably of significance in and of itself. I indicated that I considered that the Medical Director of the Southern Trust should be made aware of the governance issues I considered arose. I also expressed the view that if the urology consultants at CAH did properly engage in the regional MDM then the issues of concern would likely not reoccur.

46. I can see from subsequent emails that the position reached was that the then Belfast Trust Medical Director (Dr Tony Stephens) was going to speak to the then Southern Trust Medical Director (Dr Loughran) about the issues I had raised. I don't know what discussions did in fact take place between them, or what the Southern Trust Medical Director thereafter did following any conversation with Dr Stephens.

47. It is the case that the events of September 2010 essentially did ensure that major urology cancer surgery was thereafter performed in Belfast under the oversight of the regional MDM, which was in line with the IOG and the recommendations of the Urology Review. This in reality meant that the risks around the issues I escalated were substantially reduced by centralisation.

48. Of much less significance was the inappropriate correspondence Mr O'Brien sent to both the patients and me. It placed unreasonable pressure on me to carry out a treatment plan in two patients that was not in the best interests of the patient, and which was not supported by the regional MDM. I have provided the USI with a 27 September 2010 letter that Dr Rankin, the then Southern Trust interim Director of Acute Services, ultimately wrote to Mr O'Brien about the correspondence he had sent.

49. I did also subsequently receive an email on 3 October 2010 from the PHA's Dianne Corrigan acknowledging that the correspondence written by Mr O'Brien was not helpful. Ms Corrigan said:

> *"Dear Chris*
>
> *I meant to speak to you at Friday's meeting but did not get an opportunity. I wanted to thank you and your colleagues for accepting the CAH cancer transfers at such short notice and operating so promptly on the first couple.*
>
> *I heard from Mark Fordham that letters were sent from the CAH consultant to the patients' GPs, the patients and yourself which were not helpful. When you were going out of your way to do something which was in the best interests of the patients concerned that must have been hard to take. Things will get better."…*

2016 delay in referral of patients from CAH

50. The Urology Services Inquiry has also asked at question 6 in the section 21 notice about an issue I raised in 2016 in respect of a delayed referral of a case from CAH for consideration of cystectomy and the conducting of unnecessary tests. On 21 June 2016 I expressed my concern about this to Ms Lee, the then Oncology Service Manager in the Belfast Trust.

51. In patients with muscle invasive bladder cancer, patients treated more than 90 days after primary diagnosis show a significant increase in extravesical disease (81% vs

52%). It is therefore imperative that patients receive their radical surgical treatment as quickly as possible to ensure the best possible outcome and best chance of cure.

52. On 21 June 2016, I escalated a case to Ms Davinia Lee of the Oncology management team in Belfast as the original resection had been the middle of February 2016 but the patient was not referred to the regional MDM until towards mid-June 2016 and I saw the patient a little beyond mid-June 2016. Unfortunately, it transpired that the patient was not fit for radical surgery, but if they had been fit, it would have been early July before their surgery would have been performed, around five months since diagnosis. I contrasted this with a patient from Personal Information who had their primary resection in May 2016 and was discussed and referred on at the regional MDT towards the middle of June 2016, seen by me a little beyond mid-June 2016 and scheduled for surgery the following week. They had their radical treatment 5 weeks from diagnosis. At the time of these events Mr O'Brien was the Chair of the NICaN (Northern Ireland Cancer Network) urology network. He had held that role since January 2013. Therefore, Mr O'Brien would have been aware of the need for prompt referral for patients with muscle invasive bladder cancer and the fact that a bone scan was not recommended as a preoperative investigation.

53. Ms Lee asked me to look at the relevant patient pathway, and I set out my view in some detail on 16 August 2016. My email was passed on to Dr Mitchell who provided his own assessment, which agreed with mine. There were then exchanges about how, from a governance perspective, the matter was to be escalated to the Southern Trust. I also raised, on 18 August 2016, the issue of ensuring that any learning about the issue was shared regionally.

54. I can see from the material provided to me by the USI that Dr Mitchell did refer the matter to the Southern Trust by emailing Mr O'Brien (who may also have been the head of the local MDT at the time) and Ms McVeigh. I can see that Dr Mitchell suggested Southern Trust may want to do a case note review on the issues with a view to seeing if there was any local or regional shared learning. I am at present not sure what else occurred, or what steps the Southern Trust took in respect of the issue.

55. My recollection is that this example was not the only occasion where there was an issue with urology referral timelines from the Southern Trust. I believe these issues had been raised before with the Southern Trust by the regional MDM chair. I am not myself sure of the detail around this.

2017/2019 issue over endoscopic resection, the use of glycine, and risk of TUR syndrome

56. In view of the open questions asked of me by USI I feel bound to mention an issue that has occurred to me as I have been preparing this witness statement. It was raised with me sometime between 2017 and 2019. I am afraid I cannot be more precise about when it occurred.

57. The context is that in October 2013 the Senior Coroner for Northern Ireland wrote to Medical Directors of Health and Social Care Trusts, following the 2011 death of a woman having endoscopic gynaecological surgery. The purpose of the letter was to seek a collegiate response from Trusts to address the surgical and anaesthetic failings identified at the inquest. A copy of the letter can be found behind Tab 4. Unfortunately, I do not have any of the documents referred to in the letter. The 2011 surgery had been performed using mono-polar resection with glycine irrigation fluid (I have referred to the use of glycine earlier in this statement). It is similar to TURP surgery. Advancements in equipment technology had seen the development of bipolar resection instruments that allowed the surgery to be performed with isotonic saline irrigation. Use of this technology eliminated the neurotoxin risks of glycine and virtually eliminated the risk of TUR syndrome.

58. In 2013, I was the Clinical Director of Urology in the Belfast Trust and took the decision with my colleagues to move entirely to bipolar resection and cease using glycine irrigation in the interests of patient safety. The experience in Belfast was that this new instrumentation was very safe. Surgeons had to adapt their technique slightly when controlling bleeding but it was adopted without issue. Parallel to that, a regional approach was taken, led by Julian Johnston (then the Assistant Medical Director in Belfast Trust), to develop a regional policy on the use of irrigating fluids during endoscopic surgery (see Tab 5). There was some resistance from Urologists outside

Belfast to changing their equipment and technique, but over time there was a gradual adoption of bipolar TURP and other safe techniques such as laser prostatectomy.

59. Some years after this policy was developed I was contacted by phone by Dr Charlie McAllister, a consultant anaesthetist in CAH. I cannot be sure when exactly I received this call, but I believe it was sometime between 2017 and 2019. Dr McAllister wished to discuss TUR surgery, TUR syndrome and use of bipolar resection. He explained that they had an issue in CAH with an individual surgeon carrying out prolonged TURP resections with glycine and some "bad" TUR syndromes. He did not name the surgeon specifically. He wanted to know my experience with introducing TURP in saline. I explained that the experience in Belfast was good, that the technique was similar to monopolar TURP with glycine and that with modern equipment, in my view, it was unjustified and unsafe to continue to use glycine due to the safety profile of it as an irrigating fluid. From a personal perspective, I have carried out TURP in saline for around 10 years and see no justification for the use of glycine.

60. I cannot myself provide more detail in relation to this issue, but I have referred to it lest it is relevant to the Terms of Reference of the USI and the open questions that have been asked of me.

Conclusion

61. I have endeavoured to assist the USI through the provision of this witness statement. I hope I have answered the various questions posed to me in the section 21 notice. I have to accept that my memory will not be perfect, and consequently I may not have remembered all examples, or even remembered fully those examples that I do recall. However, I have done my best, and I will continue to assist the USI in any way I can.

Statement of Truth

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

Signed: Personal Information redacted by the USI _____

Date: 9 August 2023

S21 No 11 of 2023

Witness statement of: Mr Christopher Hagan

Table of Attachments CH1

Attachment	Document(s) Name
Tab 1	Extracts for C Hagan Guidance Notes for the Section 21 Notice No 11 of 2023 – SHSCT – C Hagan – S21 Cover Notice 11 of 2023 C Hagan USI-Terms-of-Reference – Sept 2021
Tab 2	Review if Adult Urology Services March 2009
Tab 3	NICE Improving Outcomes in Urological Cancers 2002
Tab 4	20131021 letter from Coroner Mr Leckey re I lewis
Tab 5	Policy on surgery for endoscopic tissue resection (1) Policy on the surgical management of endoscopic tissue resection

AOB10

Time Sent	26/08/2016 12:19:39
Time Received	26/08/2016 12:19:39
Time Archived	26/08/2016 12:19:54
From:	mitchell, darren < [redacted] >
To	aidan o'brien [redacted]
CC	mcveigh, shauna [redacted]
Subject:	Case for review
Attachments	[redacted] pathway.xls 33.0 KB

Aidan – this was one of the bladder cases flagged up from the review of timelines for muscle invasive bladder cancer – I think she has been seen by Chris Hagan and was deemed unfit for surgery.

We' ll review it here and I suspect you' ll want to do a case note review there and see if there is any shared learning from it either regionally or locally?

Thanks

DMM

Dr DM Mitchell FRCR
Consultant in Clinical Oncology
Northern Ireland Cancer Centre
Belfast City Hospital
Lisburn Road
Belfast BT9 7AB

☎ - [redacted]
✉ - darren.mitchell[redacted]
Secretary - elizabeth.burgess[redacted]

AOB11

Mitchell, Darren

From: Hagan, Chris
Sent: 18 August 2016 09:29
To: Mitchell, Darren; Traub, Gillian; Lee, Davinia; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Follow Up Flag: Follow up
Flag Status: Completed

The issue for me is the regional shared learning, and clinician to clinician may not capture this. Raising it as an IR1 and hoping ST then escalate to SAI may not happen and therefore no regional learning will follow. I think we should ensure that this is shared regionally.
I agree it would be useful to look back at referrals for MIBC and their timelines
The NICAN urology chair is part of the ST MDT and NICAN should also be involved in this
chris

From: Mitchell, Darren
Sent: 17 August 2016 18:42
To: Traub, Gillian; Lee, Davinia; Hagan, Chris; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Route 1 seems best. I think I would add weight to the discussion if we saw this as a trend and had evidence to that effect.

I suspect we'd see a longer lag than would be expected.

DMM

Sent from my Windows Phone

From: Traub, Gillian
Sent: 17/08/2016 18:28
To: Lee, Davinia; Mitchell, Darren; Hagan, Chris; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Hi Davinia, thanks for following this up.

I would add 2 points:

a) There should be a Consultant to Consultant discussion as Carol Anne says but should this discussion be with the MDT chair in SHSCT rather than with the individual Consultant Urologist, if the plan for this patient was agreed at MDT, rather than being the patient's urologist own treatment plan?
b) In past experience with interface incidents (which must meet criteria for an SAI) they are not the most palatable route. We could do a 3rd way – completion of a BHSCT incident report, with discussion with SHSCT clinician, and then incident report shared with them and they are asked to investigate. It also gets shared between corporate governance teams so it is formally logged. If the SHSCT then investigate it and find that it meets SAI criteria, it would then be incumbent on them to declare an SAI.

Gillian

From: Lee, Davinia
Sent: 17 August 2016 17:39
To: Mitchell, Darren; Hagan, Chris; Traub, Gillian; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Thanks Darren. I have chatted to Carol Anne and she says there are two options to raise this with Southern Trust

1) Speak directly to the colleague in the SHSCT who referred the patient (she advised discussion should be consultant to consultant) and advise of the concerns below and ask them to take forward an investigation locally
2) Report this as an interface incident with HSCB. In this scenario we complete a one page summary and submit to HSCB and they then contact the SHSCT for investigation. In either option we will need to have a discussion with the Southern Trust referrer.

Chris/Darren – would be keen to see if you have a preference?

I will ask Tracey to pull the MDT data for Jan-June 16 and pull out the muscle invasive bladder cancers – do you want to look at all Trusts or just Southern?

Thanks
Davinia

From: Mitchell, Darren
Sent: 17 August 2016 15:47
To: Lee, Davinia; Hagan, Chris; Traub, Gillian; Crawford, Jena
Subject: RE: query

Chris – I agree there is no recommendation for isotope bone scan in the regional guidelines or NICE guidelines.

1.2.8 Consider further TURBT within 6 weeks if the first specimen does not include detrusor muscle.

1.2.9 Offer CT or MRI staging to people diagnosed with muscle-invasive bladder cancer or high-risk non-muscle-invasive bladder cancer that is being assessed for radical treatment.

1.2.10 Consider CT urography, carried out with other planned CT imaging if possible, to detect upper tract involvement in people with new or recurrent high-risk non-muscle-invasive or muscle-invasive bladder cancer.

1.2.11 Consider CT of the thorax, carried out with other planned CT imaging if possible, to detect thoracic malignancy in people with muscle-invasive bladder cancer.

1.2.12 Consider fluorodeoxyglucose positron emission tomography (FDG PET)-CT for people with muscle-invasive bladder cancer or high-risk non-muscle-invasive bladder cancer before radical treatment if there are indeterminate findings on CT or MRI, or a high risk of metastatic disease (for example, T3b disease).

I think this should be flagged back to the southern trust and I would suggest to all non-regional MDTs that any muscle invasive bladder cancer on pathology should be discussed at the regional meeting at the earliest opportunity to allow early surgical assessment and guidance on role of neo-adjuvant chemo or suitability for XRT/ ChemoXRT. Scans as per guidance can occur in tandem.

The outcomes from muscle invasive bladder cancer are poor and as you have demonstrated early intervention is crucial.

Perhaps the southern team would wish to do a case note review – either as part of an MDT process review or SAI.

SAI might be more appropriate if we see this as a consistent trend – So I also agree that a review of timelines for the last 30-50 muscle invasive cases coming to central-MDT could be reviewed to identify trends.??

Happy to discuss further.

DMM

Dr DM Mitchell FRCR
Consultant in Clinical Oncology
Northern Ireland Cancer Centre
Belfast City Hospital
Lisburn Road
Belfast BT9 7AB

☎ - Personal Information redacted by the USI
✉ - Personal Information redacted by the USI
Secretary - Personal Information redacted by the USI

From: Hagan, Chris
Sent: 16 August 2016 11:01
To: Lee, Davinia; Crawford, Jena
Cc: Traub, Gillian
Subject: RE: query

Davinia – it may be more appropriate for the MDM lead to comment.

However, from the guidance:

1. I can see no role for bone scan and we do not routinely do this in Belfast. I would ask them to justify this – from the guidance:

CT imaging for local staging of MIBC: The advantages of CT include high spatial resolution, shorter acquisition time, wider coverage in a single breath hold, and lower susceptibility to variable patient factors. Computed tomography is unable to differentiate between stages Ta and T3a tumours, but it is useful for detecting invasion into the perivesical fat (T3b) and adjacent organs. The accuracy of CT in determining extravesical tumour extension varies from 55% to 92% and increases with more advanced disease.
MRI for local staging of invasive bladder cancer: Magnetic resonance imaging has superior soft tissue contrast resolution compared with CT, but poorer spatial 32 V1.3

resolution. In studies performed before the availability of multidetector CT, MRI was reported as more accurate in local assessment. The accuracy of MRI for primary tumour staging varies from 73% to 96% (mean 85%). These values were 10-33% (mean 19%) higher than those obtained with CT. Dynamic contrast-enhanced (DCE) MRI may help to differentiate bladder tumour from surrounding tissues or post-biopsy reaction, because enhancement of the tumour occurs earlier than that of the normal bladder wall, due to neovascularisation. In 2006, a link was established between the use of gadolinium-based contrast agents and nephrogenic systemic fibrosis (NSF), which may result in fatal or severely debilitating systemic fibrosis. Patients with impaired renal function are at risk of developing NSF and the non-ionic linear gadolinium-based contrast agents should be avoided (gadodiamide, gadopentetate dimeglumine and gadoversetamide). A stable macrocyclic contrast agent

should be used (gadobutrol, gadoterate meglumine or gadoteridol). Alternatively, contrast-enhanced CT could be performed using iodinated contrast media (LE: 4).

2. **Timing and delay of cystectomy:**
   Patients treated > 90 days after the primary diagnosis showed a significant increase in extravesical disease (81 vs 52%). Delay in cystectomy affects treatment outcome and the type of urinary diversion. In organ-confined urothelial cancer of the bladder, the average time from primary diagnosis to cystectomy was 12.2 months in patients who received a neobladder and 19.1 months in those who received an ileal conduit. This was even more noticeable with organ-confined invasive cancer; the average time to surgery was 3.1 months with a neobladder and 15.1 months with an ileal conduit (8). Similar results have been observed in a series of 247 patients: recurrence-free survival and OS were significantly better in patients treated before 90 days compared to others treated after 90 days.

Happy to discuss further. It may well be worth looking at other ITTs for cystectomy
chris

From: Lee, Davinia
Sent: 15 August 2016 16:08
To: Hagan, Chris; Crawford, Jena
Cc: Traub, Gillian
Subject: FW: query

Hi Chris,

Can I check if you have had an opportunity to review this patients pathway, and whether you still have concerns we need to follow up on?

Thanks
Davinia

From: Lee, Davinia
Sent: 22 June 2016 17:19
To: Hagan, Chris
Cc: Crawford, Jena; Traub, Gillian
Subject: RE: query

Hi Chris

I have had a look at the patients pathway from CaPPS, see attached.

I have compared it against the NICaN pathway (page 125 of the clinical guidelines) and the guidance is for muscle invasive bladder cancer to send to CT chest abdomen before MDT discussion, however in this case it was discussed at MDT first. There was then a delay to the bone scan and it took over a month for the CT after the first MDM and nearly 2 months from the original report of the pathology. They then discussed at local MDT again on 28/4/16 and decided on a plain film of left shoulder and central MDM discussion. The first discussion at the regional MDT was following this on 12/5 at which a CT was recommended of the shoulder. An MRI was carried out as recommended by the radiologist on 26/5 and then was discussed centrally again and transferred on 9/6/16.

Would you have a look at the pathway prior to the first central MDM discussion on 12/5 for me? It looks like a CT should have been requested following the original path on 29/2 in line with the pathway attached which would have

saved at least a month, but would welcome your clinical view as to what should have happened post original resection and pre specialist MDT discussion before we decide on how to proceed.

Thanks
Davinia

From: Hagan, Chris
Sent: 22 June 2016 10:01
To: Lee, Davinia
Subject: RE: query

Sorry its: Patient 127
chris

From: Lee, Davinia
Sent: 22 June 2016 09:13
To: Hagan, Chris
Subject: RE: query

Hi Chris

We can't find anything for patient Personal Information redacted by the USI on CaPPS or ECR – is the HCN definitely correct? What is the patients name?

Thanks
Davinia

From: Hagan, Chris
Sent: 21 June 2016 16:24
To: Lee, Davinia
Cc: Crawford, Jena
Subject: query

Davinia
I'm very concerned about delays in ITT from Craigavon and how we raise this – is it possibly an interface SAI?

patient Personal Information redacted by the USI muscle invasive bladder cancer.
Original resection16.02.206 with multiple local MDT discussions before a regional discussion 09.06.2016 and I see her today 21.06.2016. In my view there are multiple avoidable delays which will potentially lead to an adverse outcome – she is not fit for cystectomy today.

Contrast this with an exemplar. Patient Personal Information redacted by the USI TURBT 25/05/2016 in Derry. Muscle invasive bladder cancer; discussed regional MDT 09/06/2016 and seen today with radical surgery next week.

What do you think?

happy to discuss

Chris

GUIDANCE NOTES FOR THE SECTION 21 NOTICE

1. The Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust (The Urology Services Inquiry) was set up under the Inquiries Act 2005 ('the Act').

2. These Guidance Notes are not part of the Chair's Notice served under Section 21 of the Act, but are designed to assist those who receive such a Notice.

3. It is very important that a Notice served under Section 21 of the Act is complied with in full. Failure to comply has potentially very serious consequences. Failure to comply may result in you being prosecuted and convicted of a criminal offence that may result in you being fined and/or imprisoned; or being certified to the High Court where you may face contempt of court proceedings.

4. You should consult your solicitor, or your organisation's legal advisor, about the Notice as soon as possible. They will be able to assist you as to how to deal with it.

5. If you feel the content of the Notice is somehow unclear, and you wish something to be clarified, you may contact Anne Donnelly, Solicitor to the Inquiry, by email at Personal Information redacted by the USI who will endeavor to assist with your query and will discuss it with the Chair of the Inquiry, as necessary.

6. Compliance with the Notice requires you, in the case of producing documents, to have the documents with the Inquiry by the date and time set out in the Notice. Where the Notice requires you to produce a witness statement the statement should be produced to the Inquiry by the date and time set out in the Notice.

7. "Document" is defined in section 43 of the Act as information recorded in any form.

8. There is no restriction in the Act on the number of times a Section 21 Notice may be served upon a person or organisation. The Inquiry reserves the right to issue further such notices in future to any recipient, as appropriate in the judgment of the Chair.

9. The Inquiry prefers that documents, including statements, are received by it in electronic form - preferably as a PDF document - and would be grateful if you could furnish, wherever possible, the documents required of you in that form. The documents should be sent to [redacted]

10. Where it is not possible for you to send documents in electronic form you should engage with the Solicitor to the Inquiry to find a suitable solution for provision of the documents to the Inquiry. The Inquiry is keen to ensure that documents are received by it in a manner which is as conducive as possible to the effective and efficient conduct of the Inquiry's work. Where documents can be provided in chronological order, this is particularly helpful.

11. Where it is necessary to send hard copy documents, these should be sent to the Inquiry by post or courier to: **Urology Services Inquiry, 1 Bradford Court, Belfast BT8 6RB.** If there is a need to hand deliver the documents then contact should be made with the Solicitor to the Inquiry to make suitable arrangements.

12. It may be that you consider that some of the documents you are providing to the Inquiry should be redacted in some way for some reason, bearing mind that the Inquiry may decide to publish the documents in due course. If you do feel documents you are providing should be redacted in some way, then you should provide the documents to the Inquiry in provisionally redacted form (using a grey redaction if possible) so that the proposed redacted material can be read by the Inquiry team. You should also set out in writing the reasons why you consider the redactions should be made by the Inquiry. The Inquiry will then deal with the material in accordance with its Procedural Protocol.

13. If, for some reason, you wish to make a claim to the Chair of the Inquiry, under Section 21(4) of the Act, to the effect that you are unable to comply with the requirements of the Notice, or that it is not reasonable to require you to comply with the Notice, then that claim should be made in writing and addressed to the **Chair of the Inquiry.** Any such claim should be made as soon as possible after receiving the Notice, and no later than the deadline for making a claim set out in the Notice.

14. The claim should set out the grounds on which it is made, and the reasons why it is

said that you cannot, or it is not reasonable for you to, comply. The claim should be as comprehensive and detailed as possible.

15. If you are making a claim for a variation of the Notice in order to give you further time to comply, then you should set out why you need more time and indicate a date by which you say you will be able to comply, and why you say that date will be sufficient. If you can provide some of the information required within time but contend that you cannot provide all of the required information in time, this should be clearly stated and, again, detailed reasons for your contention should be put forward.

16. The Chair will determine whether to revoke or vary any Notice. In considering your claim she will take into account, amongst other things, the public interest in the information in question being obtained by the Inquiry, having regard to the likely importance of the information. Her decision will be communicated to the person making the claim as soon as is reasonably practicable.

17. A Section 21 Notice, by reason of the matters set out in section 22 of the Act, cannot require you to give, produce, or provide any evidence or document to the Inquiry if you could not be required to provide them in civil proceedings in Northern Ireland, or the requirement is incompatible with an EU obligation, or the documents are covered by public interest immunity. If you are withholding evidence or documents from the Inquiry for one of these reasons then you should notify the Solicitor to the Inquiry in writing, immediately the decision to withhold is taken, of what the material is that you are withholding and why you are claiming that that material is not required to be provided by the Section 21 Notice.

18. Section 40 of the Act provides the Chair with power to make awards for expenses, including for legal representation, incurred in complying with requirements imposed by the Inquiry. In determining whether an award should be made, the Chair will have regard to the financial resources of the applicant and whether making any award is in the public interest. The Chair does not expect to receive requests for funding from Northern Ireland Government Departments or other public bodies. If you are affected by the issue you can discuss it with the Solicitor to the Inquiry.

Mr. Christopher Hagan
Consultant Urologist
Belfast Health and Social Care Trust
Headquarters
51 Lisburn Road
Belfast
BT9 7AB

6 June 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. 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 11 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: Mr. Christopher Hagan
Consultant Urologist
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 27th June 2023.**

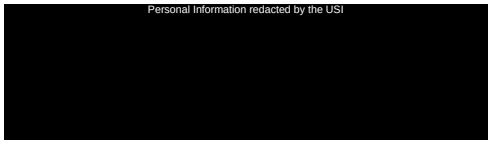
APPLICATION TO VARY OR REVOKE THE NOTICE

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 20th June 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 6th June 2023

Signed: 

Christine Smith QC
Chair of Urology Services Inquiry

SCHEDULE

No 11 of 2023

1. 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 organisation 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.

2. 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.

3. 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 explain and provide the name and role of that other person.

4. Please consider the following extracts from Dr Colin Fitzpatrick's evidence to the Inquiry and address questions (i) – (v):

   Extracts from Dr Colin Fitzpatrick's Response to Section 21 Notice:

   …**WIT-53790 paragraph 8** It occurs to me that there were a number of missed opportunities by the Trust with Dr O'Brien's case. Initially when Simon Gibson telephoned me on 7 September 2016, I recall asking if there were wider concerns with regard to Dr O'Brien's capability and I was told that there was not. My observation is that Simon Gibson cannot have been fully informed at the time he contacted me because I find it difficult to believe that there were not prior concerns about capability before this call took place. Anecdotally I understand there are individuals who worked with Dr O'Brien who had concerns about capability for a long time. I do not have any documentary evidence that these concerns were ever raised formally.

   …**WIT-62805 paragraph 4** This anecdotal information surrounding Mr O'Brien's capability was received after he had ceased practice. The source was a (now) very senior doctor in Northern Ireland who had worked with Dr O'Brien as a trainee. The informal comments were made at a meeting about something entirely unrelated. I wish to emphasise that it was a casual conversation that took place around the time that there was media coverage regarding Dr O'Brien.

   Paragraph 5 I did not take any action given that it was a passing comment and that

Dr O'Brien was not in practice when the conversation took place. I believe that he had already retired or had been suspended by the General Medical Council. I do not have access to my diary from this time, in order to put a date on the conversation. I did not bring the anecdotal information to the attention of any relevant person or body.

Extracts from Dr Colin Fitzpatrick's oral evidence to the Inquiry on 30 March 2013:

TRA-04337
Dr Fitzpatrick: Again, this was something that occurred long after my discussion with Mr Gibson and also long after my discussions with Dr O'Kane, by which time this was all in the newspapers. The problems were all over the newspaper and everybody knew about it. I had a meeting with a doctor who happened to be a urologist about an entirely unrelated issue, nothing to do with this, and I suppose as part of the chit-chat around the meeting, I asked did other urologists have concerns. This particular urologist described a number of incidents which had occurred when he was a junior doctor working in the same unit as Mr O'Brien, and he described some rather odd forms of treatment, which I don't recall because I am not a urologist and I didn't go into any great detail. But it sounded odd to me and he certainly thought it was odd. So that's I suppose where that comes from.
Mr Wolfe KC: Just to be clear, who was that?
Dr Fitzpatrick: That was a urologist in Belfast, Mr Hagan.

(i) Confirm whether the above is an accurate reflection of any discussions you had with Dr Fitzpatrick. To the extent that it is not an accurate reflection, please identify any alleged inaccuracies and offer clarification of same.

(ii) Confirm the date, or approximate date, of your discussion with Dr Fitzpatrick.

(iii) Confirm the dates when you trained in the urology department within the Trust or its predecessors.

(iv) Provide information regarding the *"concerns about capability"* you had regarding the practice of Mr O'Brien to include:

a. An outline of the dates or approximate time these concerns first arose,
b. A precise description of the concerns,
c. A description of any attempts you made to escalate or otherwise address the concerns, including the name and role of any individual to whom you escalated concerns; and
d. If you made no attempts to escalate or otherwise address the concerns, please explain why.

(v) To the extent not covered by the above, please provide information regarding the *"rather odd forms of treatment"* which you reported to Dr Fitzpatrick.

5. Following your departure from the Trust, did you identify or have escalated to you any additional concerns about Mr. O'Brien's capability. To the extent that the answer is 'yes' please give details to include:

a. An outline of the dates or approximate time these concerns first arose,
b. A precise description of the concerns,
c. A description of any attempts you made to escalate or otherwise address the concerns, including the name and role of any individual to whom you escalated concerns; and
d. If you made no attempts to escalate or otherwise address the concerns,

please explain why.

6. On 23 February 2021 Dr Darren Mitchell was interviewed by Dr Dermot Hughes in relation to the investigation of a number of SAIs concerning former patients of Mr Aidan O'Brien. The record of that interview states as follows:

> **…TRU-162276** Dr Mitchell mentioned a radical bladder cancer case in 2016, Chris Hagan and Gillian Traub noted there was a significant delay in treatment whilst waiting for a bone scan, this case was flagged back to SHSCT. Dr Mitchell believes AOB was chair of the southern urology MDM at that stage.

Please consider **WIT-96698-96703** (attached hereto) and the following extracts from Dr Darren Mitchell's evidence to the Inquiry and address questions (i) – (v):

Extracts from Dr Darren Mitchell's Response to Section 21 Notice:

> …**WIT-96670** Mr. Hagan raised concern to Ms Davinia Lee who I believe was the cancer services manager at the time about avoidable delays in the management of muscle invasive bladder case referred to him from Craigavon. His concern was around multiple discussions at the southern Trust MDM prior to the patient being referred for discussion at the regional meeting and he was concerned that the delays would adversely affect the outcome in this case. Mr Hagans email also identified the use of isotope bone scans as being outside the guidance for staging in muscle invasive bladder cancer.

(i) Please explain the significance of this case, giving further details as to the particular concerns you identified.

(ii) Outline all actions taken by yourself upon identification of the concerns.

(iii) Outline all actions taken by yourself and others to ensure that this case was escalated or raised with the Trust and the issues addressed.

(iv) Outline all actions taken by yourself and others to ensure that this case was shared regionally.

(v) Did you seek to discuss this case with Mr. O'Brien or any other individual at the Trust at any stage? To the extent that the answer is 'yes', please give details. If no, why not?

7. Please provide any further details which you consider may be relevant to the Inquiry's Terms of Reference.

NOTE:

By virtue of section 43(1) of the Inquires 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 recording. 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 Inquires 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.

TERMS OF REFERENCE FOR THE STATUTORY INDEPENDENT PUBLIC INQUIRY INTO UROLOGY SERVICES IN THE SOUTHERN HEALTH AND SOCIAL CARE TRUST

The Urology Services Inquiry (the Inquiry) was established under the Inquiries Act 2005 and will be chaired by Christine Smith QC. The Inquiry will be wholly independent and not accountable to the Department of Health, the Executive, the Assembly, or any public body.

The Terms of Reference for the Inquiry are outlined below.

(a) To review the Southern Health and Social Care Trust's (the Trust) handling of relevant complaints or concerns identified or received prior to May 2020 and its participation in processes to maintain standards of professional practice. The Inquiry shall determine whether there were any related concerns or circumstances which should have alerted the Southern Trust to instigate an earlier and more thorough investigation over and above the extant arrangements for raising concerns and making complaints.

(b) To evaluate the corporate and clinical governance procedures and arrangements within the Trust in relation to the circumstances which led to the Trust conducting a "lookback review" of patients seen by the urology consultant Mr Aidan O'Brien (for the period from January 2019 until May 2020). This includes the communication and escalation of the reporting of issues related to potential concerns about patient care and safety within and between the Trust, the Health and Social Care Board, Public Health Agency and the Department. It also includes any other areas which directly bear on patient care and safety and an assessment of the role of the Board of the Trust.

(c) To examine the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate, in order to provide a

comprehensive report of findings related to the governance of patient care and safety within the Trust's urology specialty.

(d) To afford those patients affected, and/or their immediate families, an opportunity to report their experiences to the Inquiry.

(e) To review the implementation of the Department of Health's "Maintaining High Professional Standards Policy" by the Trust in relation to the investigation related to Mr O'Brien. The Inquiry is asked to determine whether the application of this Policy by the Trust was effective and to make recommendations, if required, to strengthen the Policy.

(f) To identify any learning points and make appropriate recommendations as to whether the framework for clinical and social care governance and its application are fit for purpose.

(g) To examine and report on any other matters which the Chairman considers arise in connection with the Inquiry's investigations in fulfilment of these Terms of Reference.

The clinical practice of Mr O'Brien is being investigated by the General Medical Council (GMC) and it would, therefore, be inappropriate for the Inquiry to encroach on the GMC's remit.

The Inquiry shall submit a report as soon as practicable to the Minister for Health. Should the Inquiry as part of its investigation establish any issue of concern which it believes needs to be brought to the Minister's immediate attention, then this will be done.

Health and Social Care Board

Review of Adult Urology Services in Northern Ireland

A modernisation and investment plan

March 2009

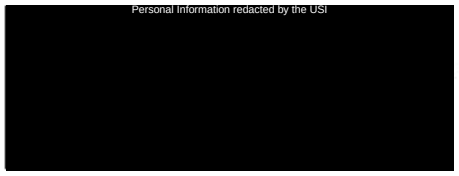
Ministerial Foreword

The health service in Northern Ireland has been able to make remarkable progress in improving access to services and sustaining the quality of those services. That work, as part of the current programme of modernisation and reform of health and social care services is ensuring that many more patients are gaining timely access to the services they need than was the case only a few short years ago. I am determined that this progress should continue.

However, whilst reducing waiting times generally there have been some concerns about the capability of our urology services as they are currently arranged, to continue to deliver care of the highest standard while striving to meet increasing demand. The capacity within the HSC to deal with an increasing demand for urology services was the principal reason why this review was commissioned.

The review considers workforce planning, training and development needs and future resourcing and proposes a model of service delivery which I am confident will produce a reformed service fit for purpose, with high quality services provided in the right place at the right time by appropriately trained and skilled staff.

Ensuring that the patients who need our health and social care services remain at the centre of everything we do is of course a fundamental step of developing and improving service provision. I hope that many of you, especially those with experience of the service, will respond with comments and suggestions which will inform the future development of this important
Speciality.



Michael McGimpsey
Minister for Health, Social Services and Public Safety

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Tables

Figures

1. SUMMARY OF RECOMMENDATIONS

Section 2 – Introduction and Context

For the purposes of this review all Urology services and Urological related procedures should be taken in the context of Adult Urology only.

1. Unless Urological procedures (particularly operative 'M' code) constitute a substantial proportion of a surgeon's practice, (s)he should cease undertaking any such procedures. Any Surgeon continuing to provide such Urology services should do so within a formal link to a Urology Unit/Team.

2. Trusts should plan and consider the implications of any impending retirements in General Surgery, particularly with regard to the transfer of "N" Code work and the associated resources to the Urology Team.

3. A separate review of urinary continence services should be undertaken, with a view to developing an integrated service model in line with NICE Guidance.

Section 3 – Current Service Profile

4. Trusts must review the process for internal Consultant to Consultant referrals to Urology to ensure that there are no undue delays in the system.

5. Northern Ireland Cancer Network (NICaN) Urology Group in conjunction with Urology Teams and Primary Care should develop and implement (by September 2009) agreed referral guidelines and pathways for suspected Urological Cancers.

6. Deployment of new Consultant posts (both vacancies and additional posts arising from this review) should take into account areas of special interest that are deemed to be required in the service configuration model.

7. Urologists, in collaboration with General Surgery and A&E colleagues, should develop and implement clear protocols and care pathways for Urology patients requiring admission to an acute hospital which does not have an acute Urology Unit.

8. Urologists, in collaboration with A&E colleagues, should develop and implement protocols/care pathways for those patients requiring direct transfer and admission to an acute Urology Unit.

9. Trusts should ensure arrangements are in place to proactively manage and provide equitable care to those patients admitted under General Surgery in hospitals without Urology Units (e.g. Antrim, Daisy Hill, Erne). Arrangements should include 7 day week notification of admissions to the appropriate Urology Unit and provision of urology advice/care by telephone, electronically or in person, also 7 days a week.

10. In undertaking the ICATS review, there must be full engagement with secondary care Urology teams, current ICATS teams, as well as General Practitioners and LCGs. In considering areas of Urology suitable for further development they should look towards erectile dysfunction, benign prostatic disease, LUTS and continence services. The review should also take into account developments elsewhere within

the UK and in particular developments within PCTs in relation to shifting care closer to home.

Section 4 – Capacity, Demand and Activity

11. Trusts (Urology departments) will be required to evidence (in their implementation plans) delivery of the key elements of the Elective Reform Programme.

Section 5 – Performance Measures

12. Trust Urology Teams must as a matter of urgency redesign and enhance capacity to provide single visit outpatient and assessment (diagnostic) services for suspected urological cancer patients.

13. Trusts should implement the key elements of the elective reform programme with regard to admission on the day of surgery, pre-operative assessment and increasing day surgery rates.

14. Trusts should participate in a benchmarking exercise of a set number of elective (procedure codes) and non-elective (diagnostic codes) patients by Consultant and by hospital with a view to agreeing a target length of stay for these groups of patients.

15. Trusts will be required to include in their implementation plans, an action plan for increasing the percentage of elective operations undertaken as day surgery, redesigning their day surgery theatre facilities and should work with Urology Team in other Trusts to agree procedures for which day care will be the norm for elective surgery.

16. Trusts should review their outpatient review practice, redesign other methods/staff (telephone follow-up/nurse) where appropriate and subject to casemix/complexity issues reduce new:review ratios to the level of peer colleagues.

17. Trusts must modernise and redesign outpatient clinic templates and admin/booking processes to ensure they maximise their capacity for new and review patients and to prevent backlogs occurring in the future.

Section 7 – Urological Cancers

18. The NICaN Group in conjunction with each Trust and Commissioners should develop and implement a clear action plan with timelines for the implementation of the new arrangements/enhanced services in working towards compliance with IOG.

19. By March 2010, at the latest, all radical pelvic surgery should be undertaken on a single site, in BCH, by a specialist team of surgeons. The transfer of this work should be phased to enable BCH to appoint appropriate staff and ensure infrastructure and systems are in place. A phased implementation plan should be agreed with all parties.

20. Trusts should ensure that surgeons carrying out small numbers (<5 per annum) of either radical pelvic operation, make arrangements to pass this work on to more

specialised colleagues, as soon as is practicably possible, (whilst a single site service is being established).

Section 8 – Clinical Workforce Requirements

21. To deliver the level of activity from 2008/09 and address the issues around casemix and complexity it is recommended that the number of Consultant Urologists is increased to 23 wte.

22. Urology Teams must ensure that current capacity is optimised to deliver the number FCEs by Consultant as per BAUS guidelines (subject to casemix and complexity). This may require access to additional operating sessions up to at least 4 per week (42 weeks per year) and an amendment to job plans.

23. At least 5 Clinical Nurse Specialists (cancer) should be appointed (and trained). The deployment of these staff within particular teams will need to be decided and Trusts will be required to develop detailed job plans with caseload, activity and measurable outcomes agreed prior to implementation. A further review and benchmarking of cancer CNS's should be undertaken in mid 2010.

Section 9 – Service Configuration Model

24. Urology services in Northern Ireland should be reconfigured into a 3 team model, to achieve long term stability and viability.

25. Teams North and East (Northern, Western, Belfast and South Eastern Trusts) should ensure that prior to the creation of the new Teams, there are clear, unambiguous and agreed arrangements in place with regard to Consultant on-call and out of hours arrangements.

26. Each Trust must work in partnership with the other Trust/s within the new team structure to determine and agree the new arrangements for service delivery, including inter alia, governance, employment and contractual arrangements for clinical staff, locations, frequency and prioritisation of outreach services, areas of Consultant specialist interest based on capacity and expertise required and catchment populations to be served.

2. INTRODUCTION AND CONTEXT

Introduction

2.1 A regional review of Adult Urology Services was undertaken in response to service concerns regarding the ability to manage growing demand, meet Cancer and elective waiting times, maintain quality standards and provide high quality elective and emergency services.

2.2 A multi-disciplinary and multi-organisational Steering Group was established under the Chairmanship of Mr H. Mullen, Director of Performance and Provider Development and this group met on five occasions between September 2008-March 2009. Membership of the group is included in Appendix 1.

2.3 An External Advisor, Mr Mark Fordham, a Consultant Urologist, Royal Liverpool and Broadgreen University Hospital Trust, was appointed and attended all Steering Group meetings and a number of other sub group sessions.

2.4 Terms of Reference were agreed (Appendix 2), with the overall purpose of the review being to;

Develop a modern, fit for purpose in 21century, reformed service model for Adult Urology Services which takes account of relevant guidelines (NICE, Good Practice, Royal College, BAUS, BAUN). The future model should ensure quality services are provided in the right place, at the right time by the most appropriate clinician through the entire pathway from primary care to intermediate to secondary and tertiary care.

2.5 A literature search of guidance and policy documents was undertaken. This included consideration of reports on previous reviews in Northern Ireland. A list of the key documents considered during this review is included as Appendix 3. Sections in italics within this report are direct quotes from these documents.

2.6 During the course of the review, a significant number of discussion papers, detailed information and datasets were collated, copies of which are not included in this report but are available on request.

Context

2.7 The speciality of Urology predominately covers the assessment, diagnosis and treatment of Urogenital Conditions involving diseases of the Kidney, Bladder, Prostate, Penis, Testis and Scrotum. Bladder dysfunction, Male and Female Continence Surgery and Paediatric Peno-Scrotal Conditions make up the rest.

2.8 Thirty years ago the field of Urology was one of the many that was the province of the General Surgeon. Since that time, Urology has developed and evolved as a separate surgical specialty. Higher specialist training in General Surgery no longer covers Urology, which now has its own training programme.

2.9 Prior to 1992, fully trained dedicated Urologists were based only at the Belfast City (BCH) and Royal Victoria (RVH) Hospitals providing a unified service to these two sites and a referral service for the rest of Northern Ireland. In 1992, Urologists were

appointed at Craigavon, Mater and Altnagelvin Hospitals. By 1999 there were ten full time Urologists in post, providing services on the above sites along with Lagan Valley and Coleraine Hospitals. In addition to these ten Urologists, there were two Consultant General Surgeons (one based in Mater, one based in Ulster) who were accredited as Urologists and whose workload was increasingly in the field of Urology. Since 2002, further appointments were made in the Belfast Hospitals, Altnagelvin and Craigavon Hospitals, along with the development of a Urology Service based in Causeway Hospital. At the time of this review 2008/2009, there is a funded establishment of 17 wte Consultant Urologists, which is in line with the recommendations of the 2000 Northern Ireland Review. However, the 2000 Review envisaged the Northern Board area Urology Services being based in Antrim Area Hospital rather than at Causeway Hospital.

2.10 Urology work can be divided into two categories;

- Medical and surgical treatment of the urinary tract, (kidneys, bladder, ureters, urethra, prostate), with these surgical procedures known as 'M'code (OPCS 4.4)
- Medical and surgical treatment of the genital and reproductive system (peno-scrotal), with these surgical procedures known as 'N'code (OPCS 4.4)

2.11 Both categories comprise elective and non-elective and cancer and non-cancer elements, albeit there are much fewer non elective and cancer cases in the 'N' code category.

2.12 In recent years, with the retirement of General Surgeons who historically undertook a substantial amount of Urology work, the number of General Surgeons who undertake urinary tract operative procedures (M Code) has significantly reduced. A small number continue to undertake diagnostic cystoscopies, which to varying degrees represents a substantial proportion of their workload. Should any subsequent treatment be required, the patient is referred into the Urology Team. A General Surgeon in the Northern Trust continues to undertake Inpatient and Day Case "M" code work in the Mid-Ulster Hospital.

Recommendation

1.	Unless Urological procedures (particularly operative 'M' code) constitute a substantial proportion of a surgeon's practice, (s)he should cease undertaking any such procedures. Any Surgeon continuing to provide such Urology services should do so within a formal link to a Urology Unit/Team.

2.13 Peno-scrotal operative procedures ('N' Code) continue to be undertaken by many General Surgeons predominately based outside of Belfast. This position is not surprising given the current number of urologists in the Southern, Western and Northern Trust areas.

2.14 Table 1 below identifies the type, volume and surgical speciality for N Code work.

Table 1 - Analysis of 'N' Code (Male Genital) Surgical Operations and Procedures Undertaken by Urologists and General Surgeons (2007/08)

Trust	Total Activity	General Surgeons	Urologists	% of 'N' Code undertaken by Urologists	Number / % undertaken as day case		V	C	H
NHSCT	807	767	40	5%	701	87%	517	129	35
SHSCT	612	521	91	15%	493	81%	314	135	36
WHSCT	614	544	70	11%	528	86%	318	143	38
SEHSCT	1244	650	594	48%	1148	92%	860	147	45
BHSCT	674	103	571	85%	407	60%	209	164	49
Total	**3951**	**2585**	**1366**	**35%**	**3277**	**83%**	**2218**	**718**	**203**

V Vasectomy
C Circumcision
H Hydrocele

2.15 Consultant General Surgeons have gained substantial experience and expertise in these procedures over the years and it is not envisaged that Trust's should make any immediate plans to pass this work onto Urologists. However, it is likely that future appointees to Consultant General Surgeon Posts, will have had little experience in undertaking such procedures and therefore Trust's will need to plan and consider the implications of impending retirements in General Surgery.

Recommendation

2. Trusts should plan and consider the implications of any impending retirements in General Surgery, particularly with regard to the transfer of "N" Code work and the associated resources to the Urology Team.

2.16 Gynaecology is another specialty which undertakes urinary tract diagnostic and operative 'M' code procedures and medical treatments for female bladder dysfunction (non cancer) and incontinence. The surgical specialty of Uro-Gynaecology has developed in the last decade, with most Trusts now having trained surgeons in post, for whom, such surgical procedures, represent a significant proportion of their surgical workload.

2.17 More complex surgical procedures are referred to Urologists and this aspect of Urology is termed as female/functional Urology. The demand for these specialist surgical services is increasing and there is a need, in some cases, to have joint working e.g. complex cancer Gynaecological Surgery and complex Urological Surgery.

2.18 Female continence (stress and urge incontinence) services (non surgical) are provided in Primary Care, Community Services and in Gynaecology Secondary Care. However, *there is evidence of large undeclared demand for continence services which is held in check by the embarrassment factor* (Action On Urology). Current services in NI are fragmented, disparate and are not managed in accordance with NICE Guidelines –Urinary Incontinence: The Management of Urinary Incontinence in Women (2006).

2.19 The referral review exercise undertaken as part of the review demonstrated that GP's are not generally referring these patients into urology and as 80-90% of such patients will not require surgical intervention, it was agreed that this service would not be considered as part of this review. However, it is clear from developments

elsewhere in the UK, that continence services can be significantly enhanced and redesigned within a multidisciplinary team model (GP's, Urologists, Gynaecologists, Physiotherapists and Nurse Practitioners) and is very suitable for development in a non secondary care environment.

Recommendation

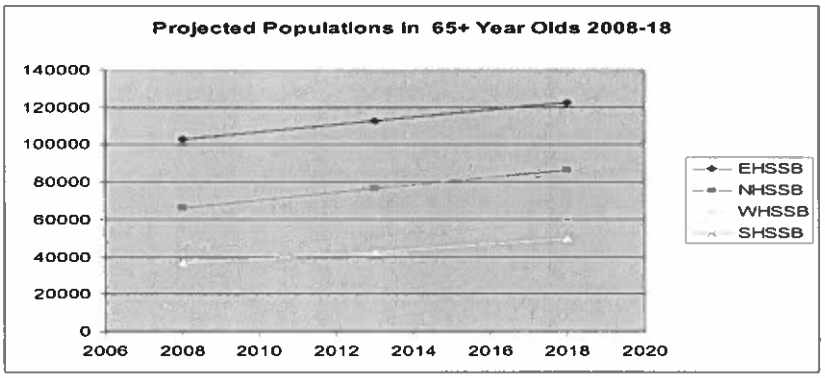
3.	A separate review of urinary continence services should be undertaken, with a view to developing an integrated service model in line with NICE Guidance.

Demography

2.20 The current population in Northern Ireland is 1.76 million with a projected rise to 1.89 million by 2018. The greatest increase will be seen in the 65+ year age group from 249,663 in 2008 to 316,548 (+27%) in 2018. This is particularly relevant for Urology as it is the ageing population that makes the heaviest demands upon Urology care (cancer and non cancer).

Figure 1

Demography 65+ years (Health and Social Services Boards)



Source NISRA

Total	249,663	282,877	316,548

3. CURRENT SERVICE PROFILE

Location of Urology Services

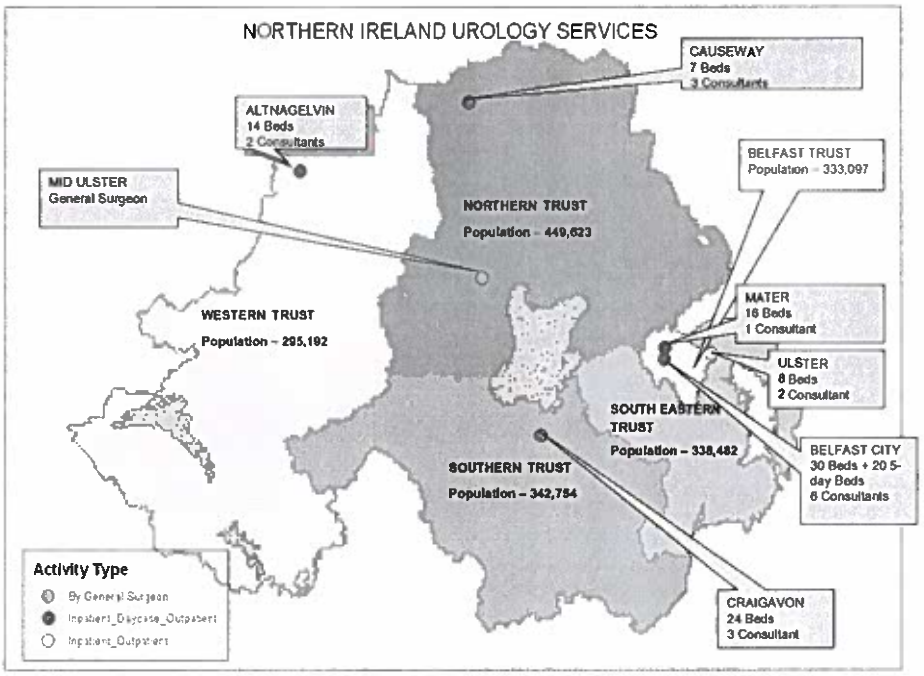
3.1 Consultant led Adult Urology Services are provided in each of the five Trusts. Table 2 below outlines the number of Consultants, Specialist Nurses and Main Hospital bases.

Table 2 – Consultant/Nurse Staffing and Inpatient Units

	Northern	Southern	South Eastern	Western	Belfast	Total
Consultants	3	3	2	2	7	17
Specialist Nurses	3	2	1	3 (2.6 WTE)	3	12 (11.6 WTE)
Hospital Base	Causeway	Craigavon	Ulster	Altnagelvin	BCH/ Mater	

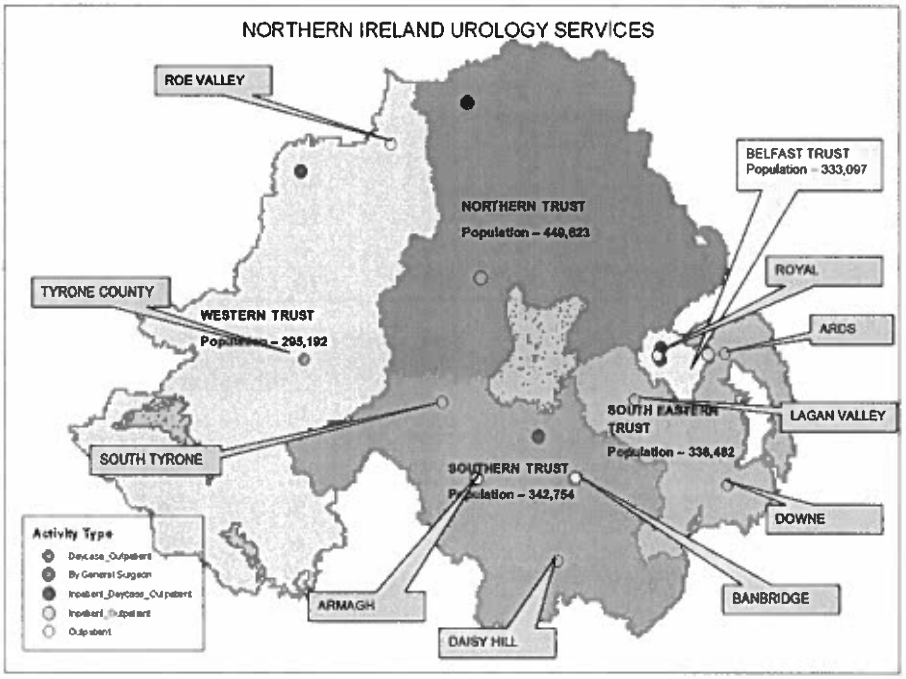
3.2 Figure 2 depicts the five Trusts, their respective resident population, and location and number of Inpatient beds.

Figure 2 – Urology Services – Inpatient Services



3.3 Figure 3 layers on the additional sites within each Trust which provide a range of Outpatient, and Day Surgical Services.

Figure 3 – Urology Services – Outpatients, Day Surgery



3.4 Figures 2 and 3 identified the resident populations for each of the 5 Trusts, however, the actual catchment populations significantly differ when adult only services and patient flows are considered. Table 3 indentifies the inpatient and day case population served by each Trust/Consultant.

Table 3 – Catchment populations served by each Trust

	Consultant urological surgeons number	Inpatient catchment population	Inpatient catchment population per consultant	Daycase catchment population	Daycase catchment population per consultant
BHSCT	7	873,000	124,700	646,000	92,300
NHSCT	3	218,000	72,700	245,000	82,000
SEHSCT	2	130,000	65,000	321,000	160,000
SHSCT	3	305,000	102,000	287,000	96,000
WHSCT	2	236,000	118,000	262,000	131,000
Total	**17**	**1,762,000**	**103,000**	**1,762,000**	**103,000**

3.5 This analysis demonstrates a significant flow of inpatient/day case work (and therefore outpatient/assessment and diagnostic workup) from the Northern Trust area to Belfast. It also demonstrates that although South Eastern Trust services a significant catchment population for day case work (and outpatient, assessment and diagnostics) it serves a smaller proportion of its population with inpatient care. This is due to the fact that a significant volume of outpatients, diagnostics and day surgery is undertaken in the Lagan Valley Hospital by a Consultant Urologist outreached from Belfast. Any subsequent inpatient treatment is then carried out in BCH.

Outpatient (new) Services

3.6 A referral review exercise was held in December 2008, at which a number of primary and secondary care clinicians (5 General Practitioners and 5 Consultant Urologists) and Trust Managers undertook a quantitative and qualitative analysis of all new outpatient referrals received (368) in Urology for a full week in November 2008.

Table 4 - Analysis of Urology Referral Letters

Gender	Belfast	Northern	Western	Southern	SE	Regional
Male	111	39	34	42	55	**281**
Female	33	13	10	11	18	**85**
Blank	0	1	1	0	0	**2**
Total	**144**	**53**	**45**	**53**	**73**	**368**

Age Range	Belfast	Northern	Western	Southern	SE	Regional
0-14	2	0	0	1	0	**3**
15-30	17	4	5	3	7	**36**
31-40	19	4	5	8	4	**40**
41-50	29	9	4	7	5	**54**
51-60	18	13	9	6	4	**50**
60+	59	22	22	28	9	**140**
Blank	0	1	0	0	44*	**45**
Total	**144**	**53**	**45**	**53**	**73**	**368**

Urgency	Belfast	Northern	Western	Southern	SE	Regional
Red Flag	6	2	3	3	4	**18**
Urgent	30	11	10	10	12	**73**
Routine	108	40	32	40	57	**277**
Blank	0	0	0	0	0	**0**
Total	**144**	**53**	**45**	**53**	**73**	**368**

Named Cons	Belfast	Northern	Western	Southern	SE	Regional
Y	35	13	6	12	15	**81**
N	109	40	39	41	58	**287**
Total	**144**	**53**	**45**	**53**	**73**	**368**

Ref Source	Belfast	Northern	Western	Southern	SE	Regional
Non-GP ref's	15	12	1	5	14	**47**
GP Ref's	129	41	43	48	59	**320**
Blank	0	0	1	0	0	**1**
Total	**144**	**53**	**45**	**53**	**73**	**368**

* 44 out of 73 referrals in SET had DOB deleted-therefore not possible to record age range.

** Data on percentages is **Appendix 4**

3.7 Regionally 76% of the referrals were male, which was to be expected. 87% of the referrals were from GPs with the remaining 13% spread across Consultant to Consultant (internal and external), A&E referrals and other sources. 78% of the referrals were referred into Urology as a specialty, with only 22% having a named Consultant. Regionally (excluding SET) 63% of the referrals related to the over 50's age range. Referrals marked by GPs as red flag or urgent represents 25%.

3.8 A breakdown of the referrals by presenting symptoms/conditions is in Table 5 below. Data on percentages is included in Appendix 5. Clinicians have indicated that this outcome is fairly representative of the nature and type of referrals they receive.

Table 5 - Analysis of presenting symptoms/conditions

Presenting Symptom/Condition		Belfast		Northern		Western		Southern		SE		Regional	
Haematuria (ALL)		19		10		10		5		12		56	
	frank		*11*		*3*		*4*		*2*		*6*		*26*
	microscopic		*6*		*5*		*6*		*2*		*6*		*25*
	blank		*2*		*2*		*0*		*1*		*0*		*5*
Prostate/raised PSA		14		7		8		9		12		50	
Other		21		4		5		8		8		46	
Ncode procedure (All)		21		2		1		3		14		41	
	vasectomy		*11*		*0*		*1*		*1*		*4*		*17*
	foreskin		*1*		*0*		*0*		*2*		*7*		*10*
	epididymal cyst		*3*		*2*		*0*		*0*		*3*		*8*
	hydrocele		*4*		*0*		*0*		*0*		*0*		*4*
	varicocele		*1*		*0*		*0*		*0*		*0*		*1*
	blank		*1*		*0*		*0*		*0*		*0*		*1*
Recurrent UTI's		17		9		4		6		4		40	
LUTS		11		7		2		5		7		32	
Prostate/BPH/prostatitis		11		5		4		6		2		28	
Renal stones/colic/loin pain		11		5		1		2		4		23	
Testicular/ Scrotal lumps or swelling		8		0		5		0		8		21	
Andrology (ALL)		7		2		3		6		2		20	
	erectile dysfunction		*2*		*2*		*0*		*3*		*1*		*8*
	Peyronie's disease		*2*		*0*		*2*		*0*		*0*		*4*
	blood in ejaculate		*3*		*0*		*0*		*0*		*0*		*3*
	ulcer/lesion on gland		*0*		*0*		*1*		*1*		*0*		*2*
	balanitis/discharge		*0*		*0*		*0*		*2*		*0*		*2*
	Blank		*0*		*0*		*0*		*0*		*1*		*1*
Unknown		3		1		1		2		0		7	
Ca Bladder/Kidney		1		1		0		1		0		3	
Blank		0		0		1		0		0		1	
Total		144		53		45		53		73		368	

3.9 The categorisation of patients by presenting symptoms/condition is a useful process and the outcomes of this exercise should assist Urology teams in determining the nature and frequency of assessment and diagnostic clinics. There was an overlap in symptoms for some patients e.g. many patients with enlarged prostate, known benign prostatic hyperplasia (BPH) or prostatitis have a range of lower urinary tract symptoms (LUTS). However, for the purposes of this exercise, if prostatic disease was identified on the referral letter, these patients were recorded as such, whereas patients presenting with just LUTS were categorised as such. Where LUTS

services are in place, both of these groups of patients are seen and treated within the same pathway.

3.10 General comments;

- A small number of the referrals (<10) were not for a new outpatient appointment but were asking for a review appointment, which was overdue, to be expedited. In addition, a small number of referrals (<10) were for patients who had been discharged from outpatients due to not responding to a booking letter or had DNA'd and who had subsequently visited their GP and asked for another referral to be processed.

- In overall terms, the quality and appropriateness of the referrals was deemed to be good. Internal referrals (A&E, inpatient etc) were often handwritten and were not as structured as GP referral letters.

- The exercise included looking at the time between the date recorded on the referral letter and the hospital date stamp indicating receipt. A significant variance between these two dates was noted in internal referrals (Consultant to Consultant). There did not appear to be any significant delays with regard to GP referrals.

Recommendation

4.	Trusts must review the process for internal Consultant to Consultant referrals to Urology to ensure that there are no undue delays in the system.

- Consultants indicated that they would routinely upgrade a significant number of routine and urgent referrals (GP) to urgent or red flag. This is particularly relevant when considering the service capacity requirements to assess and investigate potential cancers within cancer standard timescales. This has been confirmed in a recent Cancer Registry, full year analysis of the cancer waiting times database, with a total of 700 red flag GP referrals and 875 referrals which Consultants upgraded to red flag at triage recorded.

- It has been noted that the development of agreed referral guidelines/criteria for suspected Urological cancers is a priority piece of work for the recently formed NICaN Group and this should work should be advanced as soon as possible.

Recommendation

5.	NICaN Urology Group in conjunction with Urology Teams and Primary Care should develop and implement (by September 2009) agreed referral guidelines and pathways for suspected Urological Cancers.

Areas of Urology

3.11 As a specialty, Urology can be sub-divided into a number of special interest areas, most of which also comprise elements of general or 'core' Urology work.

3.12 **Core Urology** includes the assessment, diagnosis, medical treatment and (non complex and/or endoscopic) surgical treatment of diseases/conditions of the kidney,

bladder, prostate, penis and scrotum. LUTS, BPH, haematuria, simple stones, erectile dysfunction (ED) and 'N' code work are considered to be core Urology. Urologists in NI, regardless of special interest area, all provide core Urology services. Over 80% of all 'M' and 'N' code inpatient and daycase procedures are peno-scrotal, cystoscopy, TURBT (trans urethral resection of bladder tumour), TURP (trans urethral resection of prostate) and urethral catheterisation.

3.13 **Uro-Oncology.** Around 40% of Urology work is cancer related and most of the assessment, diagnostics and medical/ simple surgical treatments are appropriately undertaken at local level. Less than 10% of Urological cancers require radical/complex surgery. (see section 7).Specialist cancer services are based in BCH, where there are three designated 'cancer' Urologists. One Urologist in Altnagelvin and one/two in Craigavon would also be considered to have a special interest in cancer.

3.14 **Stones/Endourology** includes the management and treatment of renal and ureteric calculi. This involves open surgery, endoscopic intervention or stone fragmentation using multimodal techniques such as laser, lithoclast with or without US (ultrasound) and ESWL (Extracorporeal shock wave lithotripsy). Craigavon has the only fixed-site lithotripter, with BCH and Causeway serviced by a mobile facility on a sessional basis. With regard to special interest Urologists, there are currently two in Belfast Trust and one in each of the other four Trusts.

3.15 **Andrology** includes the treatment of erectile dysfunction, particularly post prostate surgery, penile curvatures and deformities (Peyronie's disease) and other conditions of the male reproductive organs. Currently all Consultants provide andrology services within their commitment to core Urology. The service would benefit from having a specialist Urologist to manage and treat the more complex cases, including penile prostheses work.

3.16 **Reconstruction,** which is often combined with the functional side of Urology, includes reconstruction of urinary continence in men, bladder reconstruction after oncological surgery and in a neuropathic bladder, e.g. spina bifida, spinal cord injury, bladder reconstruction in congenital and developmental LUT pathology (adolescent), urethral reconstruction for strictures and reconstruction prior to transplantation. There are currently two Consultants (one on long term sick leave) in Belfast who specialise in this area, working closely with the Uro-oncology team and with supra regional support provided by University College Hospital London.

3.17 **Female/functional** relates to the management and treatment of incontinence and bladder dysfunction in women, which on some occasions overlaps with reconstruction surgery. Some of this work is undertaken by Urologists however, the majority is undertaken by Uro-Gynaecologists as outlined in section 2. There is a shared view among Urologists that each Urology team should have at least one Urologist with a special interest in female/ functional Urology, and who for this aspect of their work, should work within a multidisciplinary team of Gynaecologists, physiotherapists and nurse practitioners in providing care for urinary incontinence, prolapse and fistula repair.

Recommendation

6.	Deployment of new Consultant posts (both vacancies and additional posts arising from this review) should take into account areas of special interest that are deemed to be required in the service configuration model

Non-Elective Services

3.18 There are approximately 2,500 non-elective FCE's (coded as Urology on admission or discharge) per annum (approximately 7 a day) with little variation in these numbers from year to year.

3.19 In broad terms, non-elective admissions fall into the following categories;

- Testicular torsion/infections
- Renal colic/Acute kidney obstruction
- Infection—recurrent UTI's/ pyelonephritis
- Urinary retention /haematuria

3.20 The majority of admissions fall into urinary retention and renal colic which do not usually require an immediate surgical operation, neither does treatment of infections. Testicular torsion and acute kidney obstruction require emergency (often surgical) intervention.

3.21 There are currently 15 hospitals in NI with A&E Departments (varying opening times) and acute medical and surgical facilities. With the implementation of DBS (Developing Better Services) this position will change in future years. However, for the purposes of this review the profile of services and location of non-elective Urology patients is assumed to be as is at present.

3.22 The majority of non-elective admissions are admitted to the 'presenting' acute hospital and unless it is BCH or CAH are admitted (out of hours) under General Surgery, until transfer to the care/specialty of Urology, if appropriate, on the next working day.

3.23 Even in a redesigned Urology service it is not envisaged that these arrangements will change for the foreseeable future, as it would not be viable to provide 24/7 onsite Urology cover in all 15 hospitals. However, the requirement to have clearly defined protocols and pathways in place for the management of these admissions has been identified.

Recommendations

7.	Urologists, in collaboration with General Surgery and A&E colleagues, should develop and implement clear protocols and care pathways for Urology patients requiring admission to an acute hospital which does not have an acute Urology Unit.

8.	Urologists, in collaboration with A&E colleagues, should develop and implement protocols/care pathways for those patients requiring direct transfer and admission to an acute Urology Unit.

9.	Trusts should ensure arrangements are in place to proactively manage and provide equitable care to those patients admitted under General Surgery in hospitals without Urology Units (e.g. Antrim, Daisy Hill, Erne). Arrangements should include 7 day week notification of admissions to the appropriate Urology Unit and provision of Urology advice/care by telephone, electronically or in person, also 7 days a week.

ICATS (Integrated Clinical Assessment and Treatment Services)

3.24 ICATS was launched in NI in 2005/06, as one element of the Department's Outpatient Reform Programme and in response to very lengthy waiting times for first outpatient appointments.

3.25 ICATS were designed to provide services, in a variety of primary and secondary care settings by integrated multidisciplinary teams of health service professionals, including GPs with a special interest, specialist nurses and allied health professionals. One of the fundamental elements was that many patients didn't need to be seen or assessed by a hospital Consultant at an outpatient clinic and that quick triage of referral letters and assessment and diagnostics by the most appropriate health care professional within ICATS teams, with onward referral to secondary care, only if required, would divert large numbers of outpatient referrals from hospital consultants. Another fundamental design principle was that non urgent referrals would, in the first instance, go to ICATS to be triaged and that all subsequent flows to secondary care consultants would be from the ICATS team.

3.26 It was agreed that, to begin with, ICATS would be implemented in a small number of core specialities (4) and these were identified based on those specialities with the highest volumes and longest waiting times in 2005/06. Urology was one of the 4 initial specialties identified. Across all ICATS specialties £2m was allocated in 2006/07, increasing to £9m recurrently from 2007/08.

3.27 The design of ICATS included 5 possible next steps/pathways for patients referred into the service-

- to diagnostics,
- for direct treatment on an inpatient/day case list,
- for return to primary care with advice on further management,
- to tier 2 outpatient services (non Consultant assessment and treatment) or
- to hospital (Consultant) outpatients.

3.28 For a variety of reasons, the development of Urology ICATS has been difficult, slower than planned and somewhat fragmented with regard to service model design, which differs significantly in each of the Board areas.

3.29 Table 6 below outlines the progress to date in Urology ICATS.

Table 6 - Urology ICATS - Current Position

Board Area	Current Position	Ring fenced funding/ Investment Made	Comments
NHSSB	Hospital based (Causeway) Nurse specialists undertaking mostly cystoscopies. Consultant led referral triage.	£642K	Original intention to expand nurse service to LUTS/haematuria/prostate clinics and review/follow-up clinics.
SHSSB	GPSI and specialist nurse Tier 2 clinics for haematuria, prostate, LUTS, stones, andrology. ICATS in separate building on Craigavon Area Hospital site. Consultant led referral triage.	£240K	Oncology review and urodynamics clinics being established.
WHSSB	Nurse led clinics (LUTS, prostate) and single visit haematuria clinics with nurse specialists/staff grade in place for some years. Predominately hospital based (Altnagelvin). Consultant led referral triage.	£211K	ICATS plan now approved – expanding diagnostic, LUTS services and involving GPSI'S in referral triage process in order to improve links with primary care and improve referral information and patterns.
EHSSB	SET – plan approved by EHSSB late 2008. Nurse specialist undertaking cystoscopies for some time outwith any ICATS model. BELFAST – no progress but nurse led services in place for some time and single visit haematuria clinic established late 2008. Consultant led referral triage in both SET +Belfast	£350K	GPSI'S appointed some time ago but posts not yet activated.

3.30 It is clear that Urology services have been developing non Consultant delivered outpatient, assessment and diagnostic services, such as haematuria, LUTS, ED, prostate, stones etc for some years prior to the launch of ICATS. These services were/are largely provided by nurse specialists, staff grades and radiology staff in a hospital environment.

3.31 Consultant Urologists unanimously consider that referral triage should be led by Consultants. With over 40% of referrals being cancer related (and with many not red flagged or marked urgent) they believe that they are best placed and skilled to undertake the triage process. They also believe that despite the volume of referrals, this is not a particularly time consuming process.

3.32 They indicate that they are fully committed to developing further non Consultant assessment, diagnostic and some treatment services and supportive of *providing appropriate, safe and sustainable, cost effective care closer to home, so that urology services are delivered in the right setting, with the right equipment, performed by the appropriate skilled person* (NHS, Providing Care for Patients with Urology Conditions- Guidance).

3.33 This approach was evident during the referral review exercise in December 2008, with Consultants readily indicating that patients should be booked straight into diagnostics or nurse led clinics such as LUTS, prostate, haematuria.

3.34 Consultant Urologists are very clear that the need to ensure that whoever the specialist practitioner is and wherever they work, they should be part of, or affiliated to, the local Urology team, led by a Consultant Urologist.

3.35 In light of the already changing shape of Urology services and the further developments that will arise out of this review, it is appropriate and timely to take stock of ICATS, its design principles and future development and investment. A review of all ICATS Services is planned for the first quarter of 2009/10 year and the outcomes of this review should guide the future direction of travel for ICATS services within Urology .

Recommendation

10.	In undertaking the ICATS review, there must be full engagement with secondary care Urology teams, current ICATS teams, as well as General Practitioners and LCGs. In considering areas of Urology suitable for further development they should look towards erectile dysfunction, benign prostatic disease, LUTS and continence services. The review should also take into account developments elsewhere within the UK and in particular developments within PCTs in relation to shifting care closer to home.

Links with Renal Transplantation

3.36 Renal transplantation is the definitive preferred treatment for end-stage renal failure. Kidneys for transplantation become available from either deceased or live donors. In 2006 the DOH commissioned a Taskforce to investigate and make recommendations to increase the level of organ donation. In 2008/09 the DHSSPS set a target for access to live renal transplantation and investment has been made to increase the live donor programme at Belfast City Hospital.

3.37 There are currently two wte transplant surgeons in post, a long-term locum transplant surgeon and in addition there is 0.2 wte input from an Urologist. The Urologist only undertakes live donor kidney retrieval using laparoscopic techniques, which is an essential quality component for the live donor programme.

3.38 Taskforce recommendations would suggest that cadaveric retrievals and transplantations should be increased to 50 per year (currently approximately 30) and within Priorities for Action there is a target for an additional 20 live donor retrievals and transplantations per year by March 2011. With the increase in laparoscopic live donor retrieval, additional input from Urologists may be needed and the current review of the renal transplantation service will need to take account of this requirement, along with the Urology input required if any reconstruction of the urinary drainage system is needed before transplantation.

4. CAPACITY, DEMAND AND ACTIVITY

4.1 Urology is a specialty that is categorised by high numbers of referrals for relatively simple initial diagnostics (often to exclude pathology) or surgical procedures. In addition, around 40% of Urology is cancer related and as more elderly patients are referred and treated, there is a need for follow-up services and patient surveillance.

4.2 The increasing demand for Urology services in Northern Ireland is similar to that being experienced in the rest of the UK.

4.3 The Action On Urology Team (March 2005) reported that:

Demand for Urology services is rising rapidly and the pattern of disease is changing.

- *There is an overall rise in demand from an ageing population especially the over 50's who make the heaviest demands upon Urology care.*
- *Prostate disease incidence is rising rapidly and PSA requests are generating further demand.*
- *Haematuria/bladder disease demand is also rising, stimulated by the combined availability of dipsticks and flexible cystoscopes.*
- *Work is shifting away from surgery towards diagnostics and medical treatment.*

4.4 In addition, there has been an increased "medicalisation" of Urology as the pharmacology of the urinary tract has become better understood and the increasing availability and ever improving range of drugs.

Activity/Demand/Capacity Analysis

4.5 During the review detailed analysis was undertaken by SDU and the Boards, and the following represents the most accurate information available at this time.

Outpatients

4.6 New outpatient referrals and attendances (activity) have been increasing year on year. Not all referrals result in attendance as many are removed for "reasons other than treatment" (ROTT) and are appropriately discharged from the system without having been seen.

4.7 The most recent analysis undertaken is estimating an 18% increase in predicted (GP) demand from 2007 to 2008 (2008 ROTT rates applied). This does not however represent a 'true' picture as during this period two Trusts changed their recording/management of activity from General Surgery to Urology. It has been difficult to quantify, with a degree of accuracy, the impact of these changes on the information, as increases, (albeit smaller), in General Surgery are also being estimated. Notwithstanding the above difficulty, it has been accepted that there is a significant increase in demand, which is likely to be between 10 and 15%. It has also been concluded that this increase is likely to be as a result of those factors outlined at the beginning of this section i.e. ageing population, patient expectation and demand with the increased emphasis on men's health, changing pattern of disease, availability of assessment and diagnostic modalities to exclude pathology, along with decreasing waiting times and previously unmet need.

4.8 A regional referrals management review, led by SDU Primary Care advisors is due to commence in April 2009.

Table 7 - Urology – Service and Budget Agreement Levels and Activity

	SBA (1)	07/08 Outturn (2+4)	Projected 08/09 Outturn (3+4)
Elective Inpatients	4,155	4,937 + 295(IS)	5,823+606(IS)
Non-elective Inpatients	2,109	2,369	2,496
Daycases	8,715	12,416 + 462 (IS)	13,252+1028(IS)
New Outpatients	5,824	7,593 + 571 (IS)	9,984 +519(IS)
Review Outpatients	12,566	15,967	19,224

(1) Information from 4 Boards SBAs
(2) 2007/08 outturn from PAS (includes in-house additional activity)
(3) Projected 2008/09 outturn (including in-house additional activity) based on November 2008 position
(4) IS information provided by EHSSB

4.9 In 2008, the Boards completed a detailed capacity and demand model across a number of specialities, inclusive of Urology. A number of assumptions/estimates were applied and both the recurrent gap against SBA and non-recurrent (backlog) was identified. The recurrent gap does not take account of growth in demand. The backlog (non-recurrent) gap relates to the in-year activity required due to the need to reduce waiting times for inpatient/day cases and outpatients to 13 and 9 weeks respectively by March 2009.

4.10 It has been agreed that the maximum elective access waiting times for 2009/10 will remain at 13 and 9 weeks and with a year of steady state, Trusts and Commissioners will therefore be better placed to assess both the 'real' demand and capacity to treat.

4.11 As part of this review EHSSB undertook further analysis of demand and capacity within urology and identified a significant recurrent gap, against SBA volumes.

Conclusion

4.12 Both the demand and activity in Urology is significantly greater than the current SBA volumes. Some of this is non-recurrent backlog created by the reducing waiting times since 2005/06 and the remainder is recurrent based on 2007/08 demand. Significant non-recurrent funding has been allocated in recent years to ensure Trusts were able to undertake this activity and to meet the elective access waiting times and cancer access standards. Within Trusts large numbers of additional clinics and theatre sessions have been funded non-recurrently and there has also been significant use of the independent sector.

4.13 Both increased and additional capacity to assess and treat patients is urgently required in Urology. However, additional recurrent investment in capacity (resources-human and physical) which is required in this speciality and is detailed later in this report is not the only solution. Trusts will also be required to ensure optimum use and efficiency of their existing capacity and will need to be creative in developing new ways of working and re-designing and modernising services to increase the capacity already in the system and to manage the increasing demand into secondary care.

4.14 The IEAP (Integrated Elective Access Protocol) provides detailed guidance on tried and tested systems and processes which ensure effective and efficient delivery of elective services, along with improvements to the patient experience. The Scheduled Care Reform Programme (2008-10) includes significant developments such as, pre-op assessment, admission on day of surgery, increasing day surgery rates, reducing cancelled operations, optimising the use and productivity of theatres, booking systems and a management of referral demand exercise. All of these will build/create additional capacity within the system.

Recommendation

11.	Trusts (Urology departments) will be required to evidence (in their implementation plans) delivery of the key elements of the Elective Reform Programme.

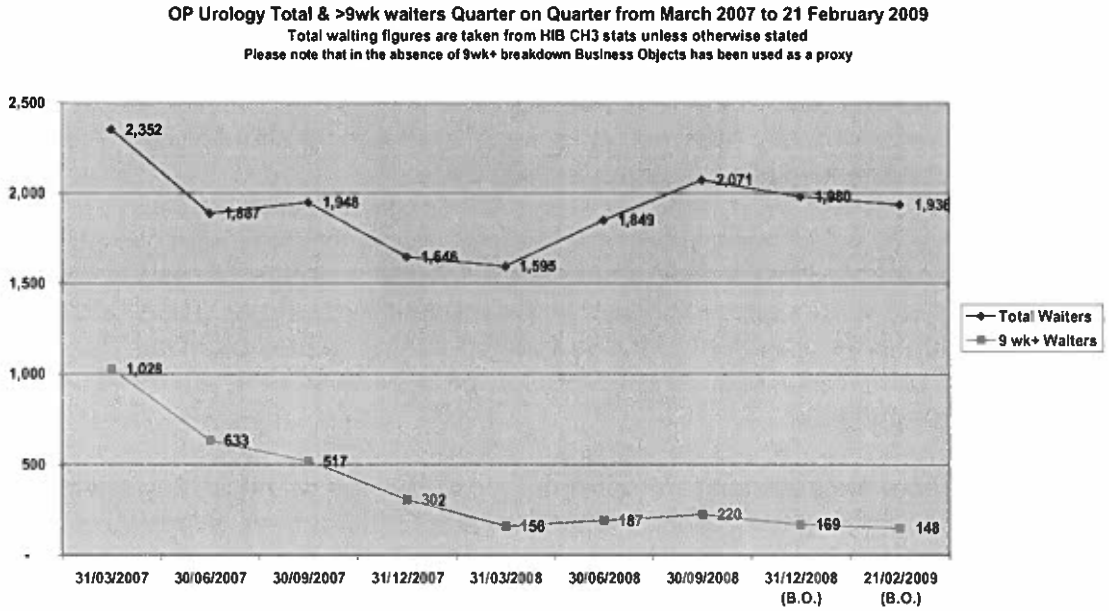
5. PERFORMANCE MEASURES

Elective access waiting times

5.1 There have been significant reductions in waiting times since 2005, in line with PFA (Priorities for action) targets and as a result of the elective reform and modernisation programme.

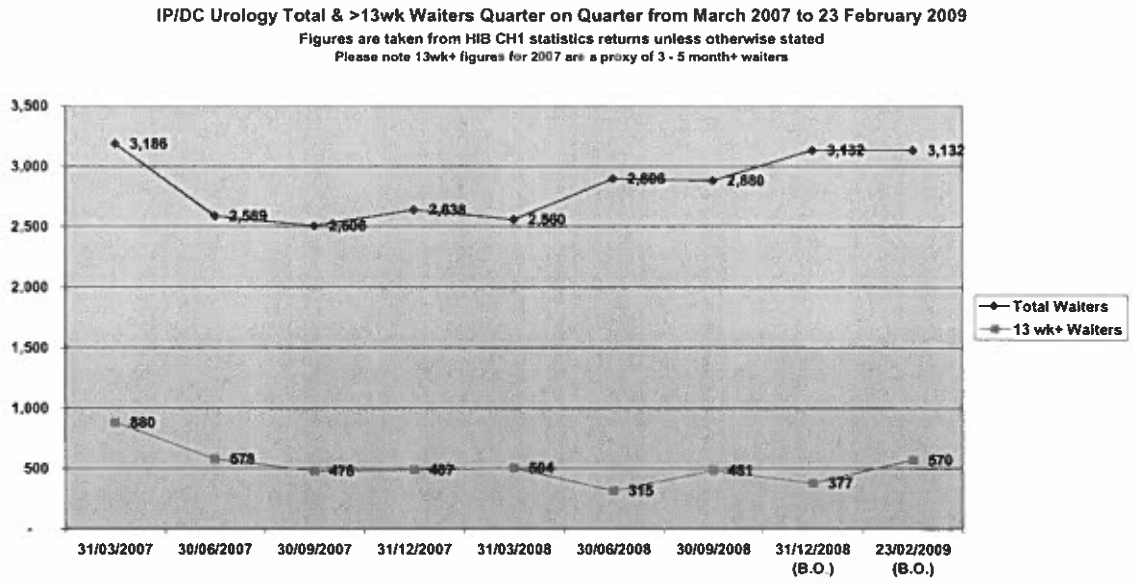
PFA 2008/2009: By March 2009, no patient should wait longer than 9 weeks for first outpatient appointment and/or diagnostics
By March 2009, no patient should wait longer than 13 weeks for Inpatient or daycase treatment.

Figure 4



(B.O. – refers to Business Objects)

Figure 5



5.2 As at February 2009, all Trusts, with the exception of Belfast, are indicating that they will meet the target waiting times for outpatients, diagnostics, Inpatients and daycases. Belfast Trust is reporting in excess of 100 anticipated breaches in Inpatient/daycase work.

Urology Cancer Performance

5.3 The Cancer Access Standards were introduced from April 2007. These introduced waiting times standards for suspected cancer patients both urgently referred by the General Practitioner or those referrals triaged by the Consultant as suspected cancer. It also set standards for those patients diagnosed with cancer and how long they should wait for treatment.

5.4 The 2008/09 Cancer Access Standards were defined as below:

- 98% of patients diagnosed with cancer from decision to treat, should begin their treatment within a maximum of 31 days
- 95% of patients urgently referred with a suspected cancer should begin their first definitive treatment within a maximum of 62 days.

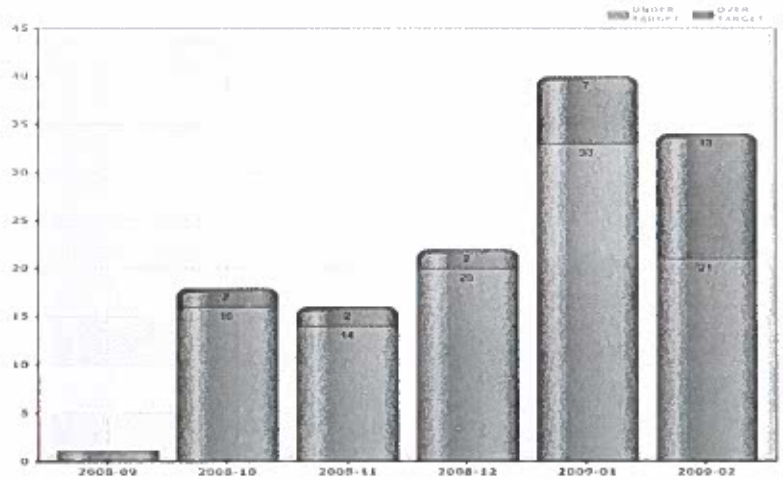
* decision to treat is the date on which the patient and clinician agree the treatment plan.

5.5 It is recognised that a considerable amount of the actions required to achieve the cancer access standards are associated with service improvement. These include the identification and agreement of the suspected cancer patient pathway, the introduction of robust administrative systems or processes and the proactive management of patients.

5.6 The recent cancer access standard performance in relation to the 62 day standard shows that up to 24 February 2009, across all Trusts, the number of Urological cancer patients achieving the 62 day standard is at 62%. This shows that of the 34 confirmed cancers treated up to this date, 13 of these had not been treated within 62 days.

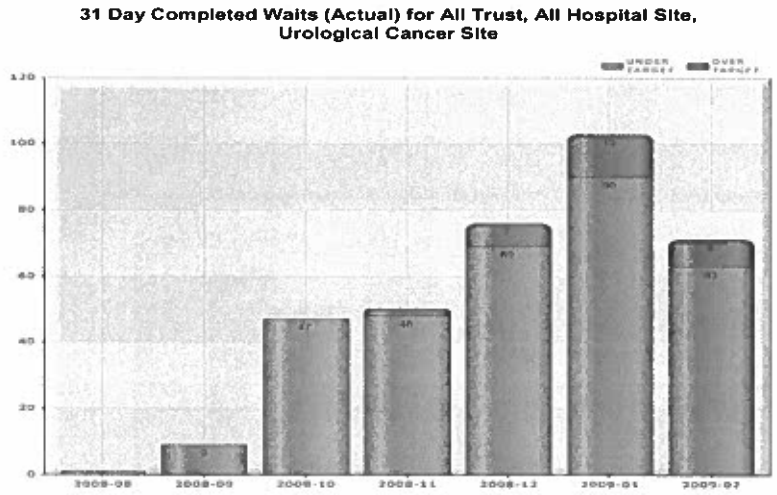
Figure 6

62 Day Completed Waits (Actual) for All Trust, All Hospital Site, Urological Cancer Site



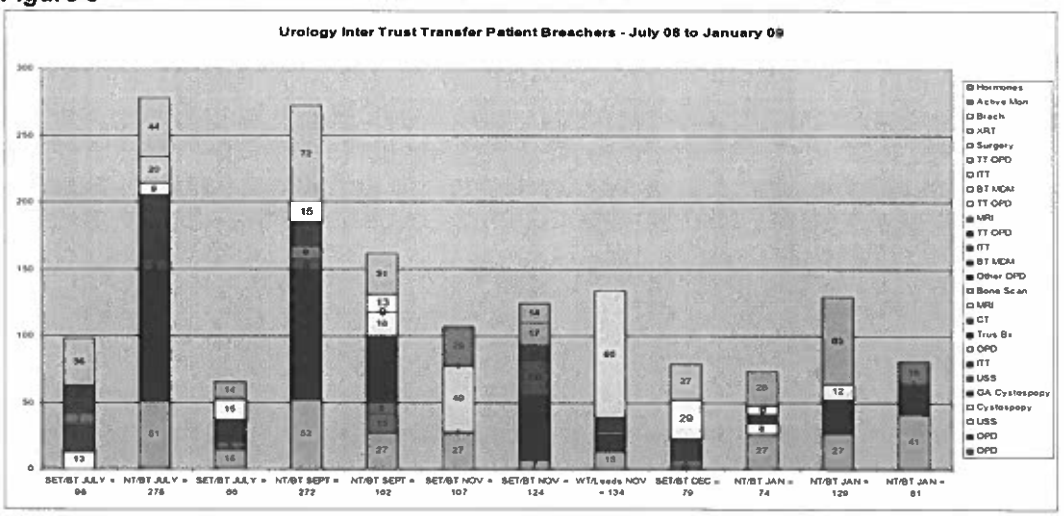
5.7 For the same period in February, the performance in relation to the 31 day standard shows that, only 87% of those Urological cancer patients (63 of 71 patients) were treated within 31 days of the decision to treat. From a sample of 9 patients that breached the 31 day standard in January 2009, they waited on average 50 days from their decision to treat to their first treatment.

Figure 7



5.8 It is accepted that those patients who transfer from one Trust to another for treatment are more likely to breach the target, than those who remain within the one Trust for their complete pathway. These patients are referred to as Inter Trust Transfer (ITT) patients. These ITT patients that breach the target are analysed in more detail. The detail for the period July 2008 to January 2009 is shown on Figure 8 below. This shows that of the suspected 'red flag' cancer patients referred who breached the 62 day target, 12 of these were ITT patients and they waited from 66 to 278 days from referral to their first treatment. It is accepted as a regional standard, for all tumour sites that if the patient is to be transferred for treatment, all diagnostic investigations should be completed and the patient should be ready for transfer by day 28 of the 62 day pathway. From this evidence it shows that this is not happening in the majority of cases.

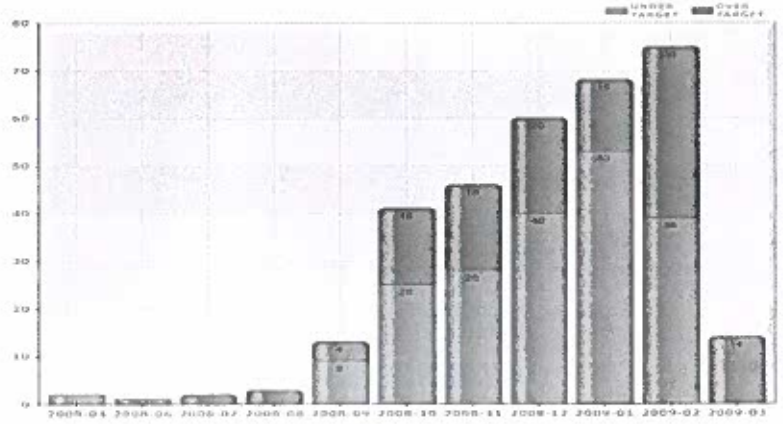
Figure 8



5.9 Whilst this analysis only refers to ITT patients, it is probably representative of the pathway for those patients that breach the target and remain only within the one Trust. For example, for the 'front end' of the patient pathway, the number of days the patient can wait for their initial outpatient appointment and subsequent investigation can be over 150 days. This has improved in recent months, but to achieve the 28 day standard this should be completed within approximately 21 days. This is further evidenced by the analysis of the 14 day waiting times for suspected Urological cancers referrals; this showed that of the referrals seen in February only 52% were seen within 14 days. As highlighted any delay at the front end of the pathway will have an impact on the Trusts ability to achieve the treatment times and the 62 day standard.

Figure 9

14 Day Current Waits (Actual) for All Trust, All Hospital Site, Urological Cancer Site



5.10 Whilst it is clear that some element of redesign of the pathway is required, the evidence appears to indicate that for the number of suspected 'red flag' cancer referrals received or triaged by the Consultants, additional capacity at the front end to complete timely investigations is required. For example, the introduction of one-stop clinics for investigations such as haematuria can have an impact and reduce the number of days the patient waits for investigations as well as reducing the number of times that the patient has to attend the hospital. This needs to be matched with sufficient Consultant capacity for treatments, including theatre capacity, Oncologists for oncology and radiotherapy.

5.11 All Trusts have reported that Urology is the key tumour site which they are at most risk with and their achievement of the cancer access standards by March 2009. In addition, at a recent ITT Executive Directors Services Steering Group the Belfast Trust reported they estimate 15 to 20 urological patients will breach the cancer access standards. Some of this is due to the late transfer of patients, but also due to a lack of available Consultants and theatre capacity. If the number of patients forecasted breach the target, this will mean that as a region NI will not achieve the cancer access standard.

Recommendation

12.	Trust Urology Teams must as a matter of urgency redesign and enhance capacity to provide single visit outpatient and assessment (diagnostic) services for suspected urological cancer patients.

NHS Better Care, Better Value Indicators

5.12 A number of better care, better value Indicators are useful performance measures to apply to Urology in assessing levels of efficiency, productivity and patient experience.

5.13 Length of stay (LOS) is one of the greatest variables between Trusts, hospitals and individual Consultants. By reviewing and improving admission and discharge processes, Trusts can improve the patient experience by reducing the number of days spent in hospital, and save bed days thus increasing capacity and saving money.

5.14 Some hospitals would expect to have longer than average LOS if they undertake more complex operations, treat patients with greater co-morbidity and patients with higher levels of social deprivation.

Table 8
Urology Episodic Average Length of Stay (06/07, 07/08, 08/09 - Apr 08 to Nov 08)

	Elective			Non Elective		
	FY2006/2007	FY2007/2008	FY2008/2009*	FY2006/2007	FY2007/2008	FY2008/2009*
Regional average LOS in days	3.7	3.4	3.2	4.8	4.7	4.6

	Elective			Non Elective		
Trust	FY2006/2007	FY2007/2008	FY2008/2009*	FY2006/2007	FY2007/2008	FY2008/2009*
Belfast Health and Social Care Trust	3.9	3.4	3.3	5.5	4.9	5.0
Northern Health and Social Care Trust	2.3	2.9	2.5	4.3	5.4	5.6
South Eastern Health and Social Care Trust	3.8	3.9	3.3	3.9	4.4	3.4
Southern Health and Social Care Trust	3.7	4.0	3.5	4.5	4.8	4.9
Western Health and Social Care Trust	3.6	2.8	3.1	3.9	3.8	3.7
Average LOS in days	3.7	3.4	3.2	4.8	4.7	4.6

	Elective			Non Elective		
Site	FY2006/2007	FY2007/2008	FY2008/2009*	FY2006/2007	FY2007/2008	FY2008/2009*
Altnagelvin Hospitals	3.6	2.8	3.1	3.9	3.8	3.7
Belfast City Hospital	4.1	3.5	3.4	5.5	4.7	5.0
Causeway	2.3	2.9	2.5	4.3	5.4	5.6
Craigavon Area Hospital	3.7	4.0	3.5	4.5	4.8	4.9
Down and Lisburn	1.0	0.0	1.2	0.0	0.0	0.0
Mater Infirmorum Hospital	3.2	2.7	2.5	5.9	6.4	5.0
The Royal Group of Hospitals	0.0	0.0	0.0	0.0	0.0	0.0
Ulster Community and Hospitals	3.8	4.0	3.5	3.9	4.4	3.4
Average LOS in days	3.7	3.4	3.2	4.8	4.7	4.6

*Information for 08/09 is cumulative from 01/04/08 to 30/11/08

5.15 All Trusts have longer average LOS for non elective patients than elective. The Southern Trust has the longest average LOS for elective patients and for elective and non-elective combined. Northern Trust has the shortest elective LOS which reflects their lower levels of major surgery.

5.16 Hospital Episode Statistics (HES) data, which combines elective and non-elective LOS, indicates a reduction in England over a three year period from an average of 3.8 days in 2005/2006 to 3.3 days in 2007/2008. Only South Eastern and Western Trusts have an average (combined) LOS of less than 4 days.

Recommendations

13.	Trusts should implement the key elements of the elective reform programme with regard to admission on the day of surgery, pre-operative assessment and increasing day surgery rates.

14.	Trusts should participate in a benchmarking exercise of a set number of elective (procedure codes) and non-elective (diagnostic codes) patients by Consultant and by hospital with a view to agreeing a target length of stay for these groups of patients.

Day Surgery

5.17 For any surgical operation there is a large variation in performance throughout the UK with regard to time spent in hospital. Some units favour certain procedures to be performed on a day case basis while others, for the same procedure may regard an overnight stay as the norm. (BADS Directory of Procedures 2007)

5.18 Hospitals are increasingly focussing on the short stay elective pathway. Carrying out elective procedures as day cases, where clinical circumstances and specialist equipment and training allows, saves money on bed occupancy and nursing care, as well as improving patient experience and outcomes.

5.19 The Audit Commission has identified 25 operations across a number of surgical specialties which could be carried out as day cases and has set a target of an average day case rate of 75% across the 25 procedures. This target has now been adopted within Priorities for Action, to be achieved by March 2011. Three of the procedures specifically relate to Urology (orchidopexy, circumcision, transurethral resection of bladder tumour). BADS (British Association of Day Surgery) identifies another 28 Urology operations (M and N code) which could be done as day surgery. The BADS Directory also suggests a % rate that can be achieved, which is 90% for the majority of the operations.

5.20 Table 9 below identifies the day case rates (% of all elective work undertaken as day case) in Urology by Trust and by hospital. It excludes Independent Sector activity and cystoscopies (M45) and prostrate TRUS, +/- biopsy (M70), both of which are not considered to be 'true' surgical operations and could equally be treated and coded as an outpatient with procedure case.

Table 9 Urology Day Case Rates excluding M45 and M70.3 & Y53.2 (06/07, 07/08, 08/09 - Apr 08 to Nov 08)
Independent Sector Activity has been excluded

	FY2006/2007	FY2007/2008	FY2008/2009*
Regional Total	50.0	48.4	48.7

Trust	FY2006/2007	FY2007/2008	FY2008/2009*
Belfast Health and Social Care Trust	47.1	42.9	46.4
Northern Health and Social Care Trust	31.1	32.6	27.9
South Eastern Health and Social Care Trust	78.0	74.0	69.9
Southern Health and Social Care Trust	43.7	45.4	49.1
Western Health and Social Care Trust	47.1	51.3	42.2

Site	FY2006/2007	FY2007/2008	FY2008/2009*
Altnagelvin Hospitals	47.1	51.3	42.2
Belfast City Hospital	49.9	45.5	48.9
Causeway	31.1	32.6	27.9
Craigavon Area Hospital	43.7	45.4	49.1
Down and Lisburn	98.8	100.0	89.3
Mater Infirmorum Hospital	4.9	4.2	6.9
The Royal Group of Hospitals	100.0	100.0	100.0
Ulster Community and Hospitals	76.6	71.2	66.3

5.21 There is a significant variation in day case rates across the Trusts/hospitals, ranging from 30% in Northern to 70% in South Eastern. Some of this can be explained due to the variation in 'N' code work undertaken by Urologists as opposed to General Surgeons (see Chapter 2). Trusts have also reported that on some sites access to dedicated day surgery facilities is limited and that this hampers the development of short stay elective pathways.

5.22 The CSR (Comprehensive Spending Review) is driving Trusts to reduce inpatient costs and to redesign/remodel their bed stock. This along with day surgery targets in Priorities for Action and the HSC Board's Elective Reform Programme will require Urology services to be creative in the development of day and short stay surgery, ensuring the provision of a safe model of care that provides a quality service to patients.

5.23 Trusts will need to consider procedures currently undertaken using theatre/day surgery facilities and the appropriateness of transferring this work to procedure/treatment rooms, thereby freeing up valuable theatre space to accommodate increased day surgery. Some operations will require specialised equipment and training for clinicians and some require longer recovery or observation times and so are only possible as a true day case if performed on morning sessions. Therefore, the development and expansion of day surgery may require reconfiguration of day surgery/main theatre lists, redesign of clinical pathways and investment in appropriate equipment/technology.

Recommendation

15.	Trusts will be required to include in their implementation plans, an action plan for increasing the percentage of elective operations undertaken as day surgery, redesigning their day surgery theatre facilities and should work with Urology Team in other Trusts to agree procedures for which day care will be the norm for elective surgery.

Outpatients

Table 10

Urology Outpatient Attendances - Consultant Led (06/07, 07/08, 08/09 - Apr 08 to Nov 08) - New : Review ratios

Independent Sector has been excluded

	FY2006/2007	FY2007/2008	FY2008/2009*
Regional new to review ratio	1.93	2.04	1.93

Trust	FY2006/2007	FY2007/2008	FY2008/2009*
Belfast Health and Social Care Trust	1.68	2.14	1.97
Northern Health and Social Care Trust	1.97	1.74	1.46
South Eastern Health and Social Care Trust	1.15	1.10	1.09
Southern Health and Social Care Trust	4.04	3.27	3.65
Western Health and Social Care Trust	2.34	2.21	2.78
Average new to review ratio	**1.93**	**2.04**	**1.93**

Site	FY2006/2007	FY2007/2008	FY2008/2009*
Altnagelvin Hospitals	2.34	2.21	2.78
Belfast City Hospital	1.84	2.90	2.44
Causeway	1.97	1.74	1.46
Craigavon Area Hospital	4.04	3.27	3.64
Down and Lisburn	1.06	1.18	1.24
Mater Infirmorum Hospital	1.63	1.11	1.47
The Royal Group of Hospitals	0.83	0.91	0.88
Ulster Community and Hospitals	1.19	1.07	1.01
Average new to review ratio	**1.93**	**2.04**	**1.93**

*Information for 08/09 is cumulative from 01/04/08 to 30/11/08

5.24 Regionally, there is an average new: review ratio of 1:2, with little variation from year to year. English HES data for 2006/07 reports a 1:2.4 new: review ratio. Variations are to be expected between hospitals and individual Consultants when case mix and complexity are taken into account e.g. BCH, due to a more complex case mix and Lagan Valley/RGH due to the fact that only day surgery is undertaken on these sites.

5.25 Craigavon Hospital is an outlier with regard to review ratios, with Altnagelvin Hospital having the second highest ratio.

5.26 It is disappointing to note that at the time of this review Trusts have reported a total of 9,386 patients for whom the (intended) date of their review has past (some by many months). This is referred to as a review backlog and if most of these patients had been seen within the same 2008/09 timeframe for the data above, then the new: review ratios would have been higher, particularly in Belfast and Southern Trusts. (Backlog; Belfast 5,599, Southern 2,309, Northern 668, South Eastern 431, Western 379). All Trusts have submitted action plans to address the review backlog that has arisen across a number of specialties.

Recommendations

16. Trusts should review their outpatient review practice, redesign other methods/staff where appropriate and subject to casemix/complexity issues reduce new:review ratios to the level of peer colleagues.

17.	Trusts must modernise and redesign outpatient clinic templates and admin/booking processes to ensure they maximise their capacity for new and review patients and to prevent backlogs occurring in the future.

6. CHALLENGES AND OPPORTUNITIES

6.1 At an early stage in the Review, an extensive round of meetings/discussion sessions were held with the various stakeholder organisations and staff to scope the challenges and opportunities of service delivery.

Challenges

6.2 A number of key themes were articulated and are summarised below:

- Increasing demand and workload pressures which were understood to be as a result of an ageing population along with people living longer, increased cancer detection and shorter waiting times arising from the elective access targets and cancer access standards, which is generating a previously unmet need in assessment and diagnostics.

- Capacity pressures (staffing), with a workforce struggling to cope with the increasing workload and meet the current targets and quality/clinical standards. This has resulted in significant reliance on independent sector and large numbers of additional clinics and theatre sessions being held internally. Both of these have been funded non-recurrently, year on year and are not sustainable in the future.

- Capacity pressures (infrastructure), on some sites, with regard to access to theatres and day surgery sessions which again results in transfer of work to independent sector. Access to elective Urology beds, in times of emergency admissions pressures, was also an issue for some sites.

- The challenges presented by the operation of 2 to 3 person Consultant teams outside of Belfast and the impact this has on on-call/cross cover arrangements, attraction and retention of clinical staff and the opportunity to develop sub specially interests and expertise. The size of the team is directly linked to its catchment population and the viability and sustainability of Urology services is dependent on a critical mass of work, of sufficient variety of conditions and treatments, to attract both training and substantive posts. The arrangements for the management and admission of acute Urological patients, particularly out of hours, in some Trusts, and the impact that the lack of such a service has on other sites was also raised as an issue.

- Impact of junior doctors hours, EWTD (European Working Time Directive) and in particular, changes to the training programme have resulted in a reduction in "the medical workforce", a shift from Consultant led services to Consultant delivered services and additional requirements on Consultants to directly provide and supervise training opportunities.

- Challenges around the cancer agenda and in particular, compliance with IOG (Improving Outcomes Guidance) and preparing for the Peer Review Exercise in 2010.

- Concerns were expressed about how service development tends to take place within and is restricted by Trust/Organisational boundaries. Also about inconsistent access/pathways for patients.

Opportunities

6.3 Within the various service and staff groups there was a strong desire and commitment to making significant improvements to Urology services in Northern Ireland.

6.4 There was general acceptance that additional investment was not the only solution: Making better use of the existing resources was also necessary and that the review of Urology services created significant opportunities to develop and re-design services, provide high quality, timely and cost effective services to patients and the community and to support and develop the individual and teams within this important specialty.

6.5 There was also a strong sense of wanting to do things differently and of the need to change and adapt to a changing landscape in terms of public expectations, targets and standards, changing pattern of disease and treatment, new technologies and techniques and employment and training legislation and entitlement.

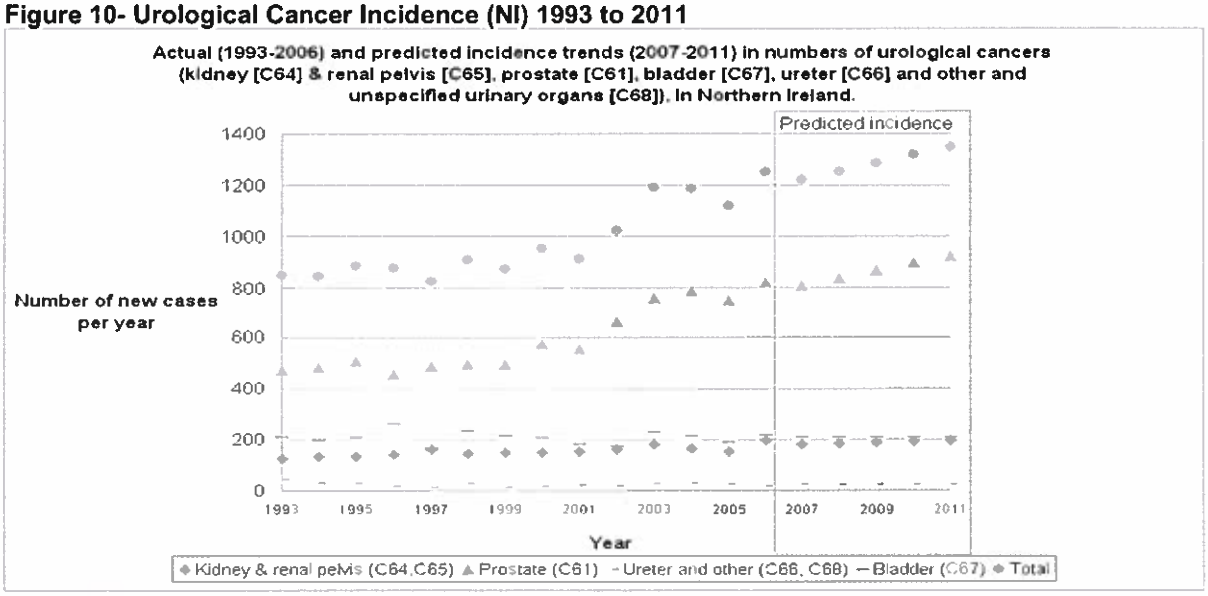
7. UROLOGICAL CANCERS

7.1 Around 40% of Urology work is cancer related and in addition to intensive assessment, diagnostics and treatment requirements, there is also a requirement for considerable patient follow-up, support and surveillance services. Cancer becomes more common with increasing age with almost 2 out of every 3 cancers diagnosed in people aged 65 and over.

7.2 Cancer of the prostate, testis, penis, kidney and bladder as a group has the highest volume of cancer incidence than any other specialty, with 1,246 incidence recorded on the cancer registry for 2007. The next highest is breast, followed by colorectal and lung.

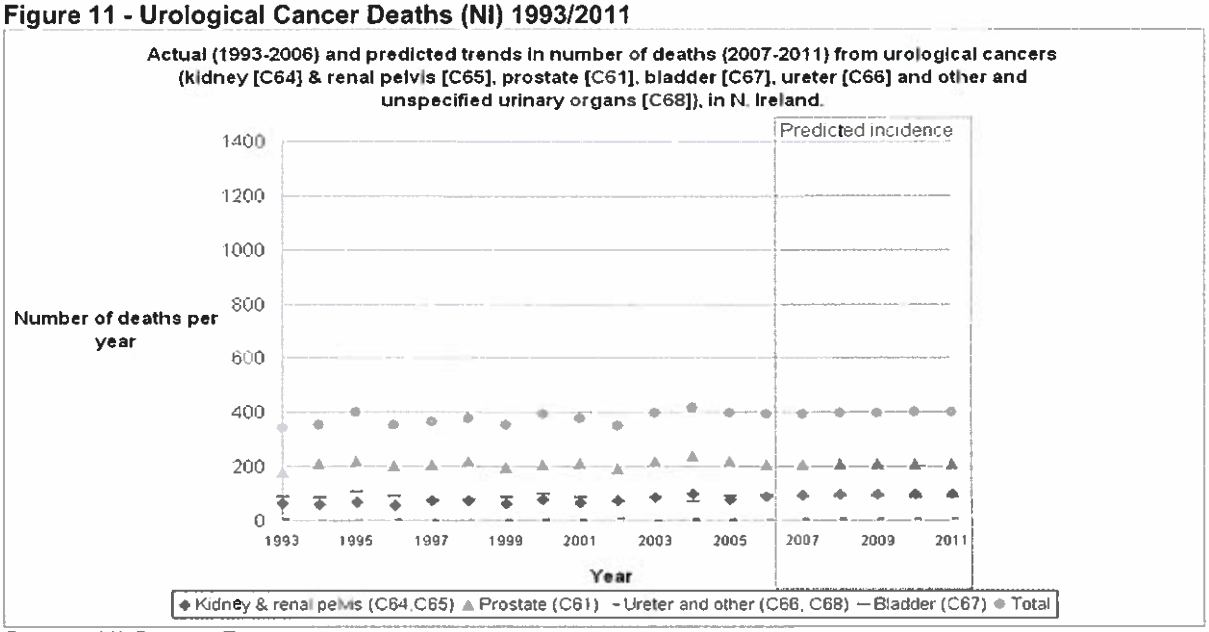
Cancer Incidence and Mortality

Figure 10- Urological Cancer Incidence (NI) 1993 to 2011



Source: NI Cancer Registry

Figure 11 - Urological Cancer Deaths (NI) 1993/2011



Source: NI Cancer Registry

7.3 Bladder and ureter incidence has been and is likely to remain stable (approximately 230).

7.4 Kidney cancer incidence has increased by almost 50% between 1993 and 2006 (196 in 2006), with a corresponding rise in deaths. By 2011, there could be further slight increases.

7.5 Prostate cancer incidence increased by 70% between 1993 and 2006 (817 in 2006). By 2011, it is predicted to increase by a further 20% compared with current incidence, but the number of deaths remains stable.

7.6 Prostate cancer is the second most frequently diagnosed cancer among men of all ages; testicular cancer, although relatively infrequent, is nevertheless the most common cancer in men under 45 years of age. Cancer of the penis, by contrast, is rare. Cancers of the kidney and bladder are roughly twice as common among men.

7.7 The main presenting symptoms of primary urological tumours fall into 3 groups:

- Lower urinary tract symptoms
- Haematuria and
- Suspicious lumps.

7.8 Haematuria is the most common symptom of both bladder and kidney cancer, although kidney cancer is often asymptomatic until it reaches a later stage.

7.9 Early, asymptomatic prostate cancer is being diagnosed more in recent years due to increase use of PSA testing and men's health awareness programmes.

Guidance and Standards

7.10 The NI Report "Cancer Services: Investing in the Future" (The Campbell Report) published in 1996 recommended that delivery of cancer services should be at three levels: Primary Care, Cancer Units and the Cancer Centre. The 2000 Review of Urological Services in Northern Ireland endorsed the principles of the Campbell Report and took account of them in their recommendations.

7.11 In 2002, NICE published guidance on cancer services-"Improving Outcomes in Urological Cancers-The Manual" (IOG).

7.12 The key recommendations from IOG are in Appendix 6. The recommendations relate to the requirement to have dedicated, specialist, multidisciplinary Urological cancer teams, making major improvements in information and support for patients and carers, with nurse specialist having a key role in these services, and having specific arrangements in place to undertake radical surgery for prostate and bladder cancer.

7.13 In 2008, under the auspices of NICaN (Northern Ireland Cancer Network) a new Urological tumour group was set up and has to date met on three occasions. Mr H Mullen chairs this group with Mr P Keane, Consultant Urologist, Belfast Trust, serving as the lead clinician. Mr Keane is also a member of the Review Steering

Group (as a NICAN lead) along with Dr D Hughes, NICaN Medical Director and Mrs B Tourish, NICaN, Clinical Network Co-ordinator.

7.14 The NICaN Group has agreed priority areas of work, based on IOG, including the development and implementation of formal dedicated MDTs / MDMs, implementing referral guidelines and agreed pathways for diagnostics and treatment of each of the cancers, developing patient information and guidance and ensuring suitable arrangements are in place prior to the Peer Review planned for 2010.

Recommendation

18. The NICaN Group in conjunction with each Trust and Commissioners should develop and implement a clear action plan with timelines for the implementation of the new arrangements/enhanced services in working towards compliance with IOG.

7.15 A key element of IOG is the requirement to undertake radical pelvic surgery on a single site, serving a population of 1 million or more, in which a specialist team carries out a cumulative total of at least 50 such operations (prostatectomy (M61)and cystectomy (M34) per annum.

7.16 Tables 11 and 12 outline the number of radical pelvic operations carried out in 2006/07 and 2007/08 by Trust and Consultant.

Table 11 – Radical Pelvic Surgery 2006/07

Trust	Consultant	M34 Bladder	M61 Prostate	Total
BHSCT	Cons A	3	11	*14*
	Cons B	8	14	*22*
	Cons C	9	11	*20*
	Cons D	5	0	*5*
Total		**25**	**36**	***61***
SHSCT	Cons A	3	1	*4*
	Cons B	8	5	*13*
	Cons C	2	5	*7*
Total		**13**	**11**	***24***
WHSCT	Cons A	3	17	*20*
Total		**3**	**17**	***17***
Grand Total		**41**	**64**	***105***

Table 12 – Radical Pelvic Surgery 2007/08

Trust	Consultant	M34 Bladder	M61 Prostate	Total
BHSCT	Cons A	6	12	*18*
	Cons B	7	18	*25*
	Cons C	20	12	*32*
	Cons D	3	0	*3*
	Cons E	1	0	*1*
Total		**37**	**42**	***79***
SHSCT	Cons A	0	1	*1*
	Cons B	3	1	*4*
	Cons C	5	3	*8*
	Cons D	0	3	*3*
Total		**8**	**8**	***16***
WHSCT	Cons A	0	7	*7*
Total		**0**	**7**	***7***
Grand Total		**45**	**57**	***102***

7.17 The Northern and South Eastern Trust do not undertake such operations and patients requiring/choosing radical surgery are referred to BCH.

7.18 In 2007/08 77% of radical pelvic operations were undertaken in Belfast Trust (BCH). Neither the Southern or Western Trust (separately or together) undertake the required number (50) of such operations. Four of the existing Consultants undertake small (<5) numbers of each of the procedures. With a total of just over 100 procedures a year, a population less than 2 million and, with the potential for this activity to reduce with the implementation of a brachytherapy service in the next year, a single site for radical pelvic surgery is considered to be the appropriate way forward if IOG compliance is to be achieved.

Recommendations

19.	By March 2010, at the latest, all radical pelvic surgery should be undertaken on a single site, in BCH, by a specialist team of surgeons. The transfer of this work should be phased to enable BCH to appoint appropriate staff and ensure infrastructure and systems are in place. A phased implementation plan should be agreed with all parties.

20.	Trusts should ensure that surgeons carrying out small numbers (<5 per annum) of either radical pelvic operation, make arrangements to pass this work on to more specialised colleagues, as soon as is practicably possible, (whilst a single site service is being established).

8. CLINICAL WORKFORCE REQUIREMENTS

Consultant staffing

8.1 In 1996, BAUS (British Association of Urological Surgeons) recommended a Consultant: Population ratio of 1:80,000 by 2007. In 1999 the ratio in Northern Ireland was 1:167,000 population reducing to 1:103,000 population at the time of the review in 2009, with a funded establishment of 17 wte Consultants.

8.2 In the 2000 "Report of a working group on Urological Services in Northern Ireland" a ratio of 1:100,000 population was recommended due to Northern Ireland's younger age profile. BAUS had indicated that the demand for Urological Services is related to the age structure of the population and specifically with the proportion of 65 years.

8.3 In 1996, the percentage of those aged 65 years and over in Northern Ireland was 12.85% and at this time was considerably lower than in England (15.8%) and Wales (15.2%). By 2007 Northern Ireland's percentage of over 65 had risen to 14.1% and is predicted to rise further to 16.7% by 2018.

8.4 A total population of 1.76 million in 2008 and a Consultant to population ratio of 1:80,000, would equate to a funded establishment of 22 wte Consultant Urologists.

8.5 The NI Urology SAC (Specialist Advisory Committee), in estimating the number of higher specialist trainees required by 2018, have used a Consultant Urologist workforce of 38 wte by 2018. In projecting future staffing, SAC took account of "Developing a Modern Surgical Workforce" published by the Royal College of Surgeons in England (2005) and subsequent interim review of October 2006. The Royal College suggests that for a population of 1 million the requirement will be 8-9 specialist surgeons and 8-10 generalists.

8.6 Based on an average age of retirement of 60 years of age, the anticipated retirements in Urology between 2009 - 2018 is four. Taking this into account along with the Royal Colleges projected future staffing requirements, SAC have recommended an increase in the number of higher specialist trainees from the current 8 at ST3+ (year 3 and above) to up to 15 by 2018.

8.7 SAC have confirmed that they are content, at this time, with the Consultant to population ratio proposals within this review i.e. 1:80,000.

Consultant Programme

8.8 Guidelines for a Consultant job plan (agreed by the Royal College of Surgeons and adopted by the Association of Surgeons of Great Britain and Ireland) are based on a commitment of 10 notional half days.

8.9 The traditional Consultant contract has 6 + 1 (special interest) fixed sessions with 3 flexible sessions. BAUS Council recommend a 5 + 1 fixed session contract with 4 flexible sessions for Consultant Urologists.

"A Quality Urologist Service for Patients in the New Millennium - Guidelines on Workload, Manpower and Standards of Care" (BAUS 2000) recommends a typical job plan as outlined below:

Operating Theatre	3 NHD
Outpatient Clinics	2 NHD
Specialist Interest	1 NHD
Ward Round plus on-call	1 NHD
Post Graduate Education:	1NHD

To Include:

- Audit, teaching
- Pathology and X-ray meetings
- Clinical Governance
- Quality Assurance
- Mortality and Morbidity meetings

Flexible commitment	2 NHD

On-call rota 1:5

- *Special interest sessions may be used to provide additional operating, specific outpatient clinics, uro dynamics, lithotripsy or to supervise the research activities of the Department.*
- *Involvement in clinical management, audit and clinical governance will occupy significant clinical time and provision must be made for these activities within the job plan, as should participation in MDM's for all Urologists.*
- *Flexible sessions cover duties, which may be performed at different times, over different weeks and even sometimes outside standard working hours. These will include clinic administration, travel, inter-departmental referral and continuing clinical responsibility. They will also include time spent after operating sessions and clinics "tidying the desk", talking to patients relatives, visiting patients on the ward prior to operation, reviewing patient notes, results and ensuring that these are made known to patients and to the relevant medical practitioners.*

Workloads

8.10 Both BAUS and The Royal College of Surgeons outline similar workloads/activity that can be expected from a Consultant's working week, based on a 42 week working year.

8.11 **Outpatients (new and review) -** A Consultant working alone should see between 1176 and 1680 patients per annum. *Consultants with a major sub specialty interest e.g. oncology, will see significantly fewer patients due to case complexity and a need to allocate more time to each patient. Teaching, particularly under graduates and house officers, will also reduce the number of cases per clinic.*

8.12 To allow sufficient time for proper assessment and counselling, it is accepted practice to allow approximately 20 minutes for a new patient consultation and 10 minutes for a follow-up consultation. Therefore in a standard clinic an Urologist, working on his own should see 7 new patients and 7 follow-up patients. This can be

adjusted locally depending on case complexity up to a maximum of 20 patients (new and review) per clinic.

8.13 **In patient/day case activity -** *The average Consultant Urological Surgeon, and his team, should be performing between a 1000 and 1250 inpatient and day patient FCEs per annum. The exact number will depend on sub specialty interest, case mix, the number of operating sessions in the job plan and whether the Urologist has an obligation to train a specialist registrar. For example, some specialists in oncology, who perform lengthy complex procedures, would be expected to have fewer FCEs than their generalist counterparts.*

8.14 The activity analysis outlined in section 4 of the report outlines projected activity of 21,571 episodes in 2008/09. This figures includes in-house additional activity provided by Trusts but excludes activity sent out to the Independent Sector. With no further reduction in elective waiting times in 2009/10, it will be possible to make a more robust assessment of recurrent demand during the year.

8.15 The activity delivered by Trusts in 2008/09 equates to 21.5 wte consultant staff, taking account of the average workload figures above. However, due to complexity/casemix issues not all Consultants will perform the average number of FCEs. For example, with the creation of single site for radical pelvic surgery there will be a requirement for an additional Uro-oncology Consultant at the BCH.

Recommendation

21.	To deliver the level of activity from 2008/09 and address the issues around casemix and complexity it is recommended that the number of Consultant Urologists is increased to 23 wte.

8.16 This level of investment in staffing infrastructure will allow Urology services to be recurrently provided at 2008/09 outturn levels. In terms of future proofing, Trusts will be required to look at further efficiencies within existing capacity with a view to increasing the average workload per Consultant to the higher level in the context of changing demographics with an older population which will place additional demands on Urology services over the coming years. This is particularly relevant to the Northern and Southern Trusts where Consultant workloads are significantly below their peer colleagues and BAUS guidelines.

Recommendation

22.	Urology Teams must ensure that current capacity is optimised to deliver the number FCEs by Consultant as per BAUS guidelines (subject to casemix and complexity). This may require access to additional operating sessions up to at least 4 per week (42 weeks per year) and an amendment to job plans.

Nurse Staffing

8.17 The additional nursing and support staff requirements to support the additional clinics and theatre sessions that will be implemented with the appointment of new Consultants are included in the estimated costing in Appendix 7.

8.18 To ensure high quality nursing services and effective and efficient use of highly specialised equipment and instruments it is essential that nurses working in Urology wards, theatres and other departments are fully trained and competent in the field of Urology.

8.19 Specialist nurses and practitioners have a key and expanding role to play in a modern Urology Service. There are many examples of nurses, within and outwith ICATS teams, undertaking assessment, diagnostic, treatment and follow-up of areas of Urology such as erectile dysfunction, LUTS (Lower Urinary Tract Symptoms), haematuria clinics, stones etc.

8.20 Specialist (Uro-Oncology) nurses must be dedicated, fully participating members of any cancer MDT, actively represent the patient's interests at MDM's and have a key role to play in carrying out detailed assessment of patients needs in order to provide, or coordinate good care. They have a particular role to play at "results" clinics and in assisting patients and carers in making informed decisions and choices regarding treatment options, the management of and living with the symptoms and consequences of their cancer and the treatments/interventions.

8.21 Under the auspices of NICaN, in collaboration with the senior nurses for cancer services across the Northern Ireland and English networks, a number of cancer site specific, clinical nurse specialist benchmarking censuses have been completed. There are a total of 12 specialist nurses in Urology in Northern Ireland at this time. However, few of these staff are solely dedicated to cancer care and therefore an estimate of the wte (whole time equivalent) has been made. In November 2008 there were estimated to be 4 wte oncology nurse specialists -1.5 in BCH, 2 in Altnagelvin and .5 in the Ulster.

8.22 Table 13 below outlines the results of a benchmarking exercise completed in November 2008, in which each of the cancer networks identified the incidence of cancer and calculated an average caseload per Clinical Nurse Specialist (CNS).

Table 13 - CNS caseload benchmarking data

	Lung	Breast	Urology	Colo-rectal	Gynae	Upper GI	Haem	Skin	Head & Neck	Brain
Cancer incidence	845	1,031	1,246	995	450	562	411	208	127	109
Total no CNS in post 2008	7.5	14	4	3	2	1	3	3	2	1
NI mean caseload	112	73	311	331	225	562	137		63	109
England mean caseload	122	81	131	89	77	98	70		66	81
Additional nos needed	3	2	5	4	4	3.5	5	1	2.5	1
Future NI mean caseload	80	64	138	142	75	125	52		51	54.5

8.23 There are higher numbers of Urological cancer incidences than in any other speciality and these CNSs have the third highest (upper GI is the highest at 562) mean caseload at 311, which is more than double the English mean caseload.

8.24 This shortfall will need to be addressed if significant improvements are to be made in the cancer pathways, waiting times, support and follow-up for Urology patients in Northern Ireland.

Recommendation

23.	At least 5 Clinical Nurse Specialists (cancer) should be appointed (and trained). The deployment of these staff within particular teams will need to be decided and Trusts will be required to develop detailed job plans with caseload, activity and measurable outcomes agreed prior to implementation. A further review and benchmarking of cancer CNSs should be undertaken in mid 2010.

Radiology Staffing

8.25 The assessment and diagnostics of Urological diseases/conditions involves intensive and high volumes of radiology services across a broad range of modalities-ultrasound (KUB, TRUS), IVP, CT and MRI scans, along with the provision of an interventional radiology service. As Urology services are redesigned and streamlined, radiology services will be required to respond and adapt to the new service models and pathways and in particular accommodate more single visit haematuria, LUTS, prostate and stones clinic.

8.26 In addition to any further investment, radiology services will be required to ensure optimum and enhanced use of current available capacity by modernising and reforming the systems and processes currently in place.

8.27 In recognition of the significant capacity gap in Urology to meet the growing demand, a number of additional Consultants will be appointed and a significant number of additional patients will need to be assessed and treated internally. Additional radiology staffing to support these appointments (included in the estimated costs in Appendix 7) has been calculated using the Adenbrookes formula of .3 wte Consultant Radiologist per wte Consultant Urologist and a ratio of 6 wte band 5 Radiographers per wte Radiologist.

Pathology and Radiotherapy Services

8.28 It is recognised with the volumes of Urological cancers, the Urology service is a high user of both pathology and radiotherapy services. However, given the work being undertaken by NICaN, within the Cancer Services Framework and the supporting cancer investment plan, and the Pathology Services Review, published in December 2007, it was agreed that the current Urology review would not include a detailed assessment of these services. Investment in an additional band 7, BMS is however included in the estimated costs in appendix 7, in recognition of the increased diagnostic workload associated with growing PSA work and the centralisation of radical pelvic surgery on the BCH site.

9. SERVICE CONFIGURATION MODEL

9.1 In section 6 the key challenges currently being faced by the service were outlined. In summary, these related to the capacity to deliver a modern, quality service and the ability to achieve and sustain long term stability and viability, with a stable workforce that can continue to attract the necessary expertise across all of the professions.

9.2 It has been recognised that investment in additional capacity and staff will not on its own resolve the challenges relating to long term service stability. This will require a reconfiguration of teams/services into more sustainable units thus enabling the service to make the best use of any investment made.

9.3 A number of models (6) for future service delivery were developed. These ranged from 5 teams in NI, with each Trust having its own discrete urology service and its staffing and workload based on its current catchment population, to 2 teams in NI.

9.4 A sub group of clinicians, Trust and Board Managers developed criteria and a weighted scoring system against which each of the models could be assessed. The 5 criteria (Appendix 8) were:

- Service stability/sustainability (population, team size, dedicated skilled radiology and nursing staff, rotas and EWTD.
- Feasibility (ease and speed of implementation).
- Compliance with DHSSPS policy/strategy, commissioner intent/support, compatibility with Trusts strategic development plans and impact on other services.
- Inpatient accessibility.
- Organisational complexity.

9.5 At the Steering Group meeting on 20 January 2009, each of the 6 models was evaluated against the agreed criteria. Model 3 (Appendix 9) was agreed as the preferred model and was deemed to be the most appropriate way forward for urology services.

Recommendation

24.	Urology services in Northern Ireland should be reconfigured into a 3 team model, to achieve long term stability and viability.

9.6 Model 3 comprises 3 teams, which for ease of description are called Team North, Team South and Team East. Table 14 below outlines the main elements of each of these teams.

Teams	Geographical Area/ Catchment Population	Consultant Staffing/Suggested Special Interest Areas**	Arrangements for Elective and Non Elective Services
Team North	Upper2/3rd of Northern* and Western integrate to form one Team/Network. Catchment population circa 480,000	Six wte All core Urology Uro-oncology – 2 Stones/endourology – 2* Functional/female Urology – 1 Andrology – 1	One on-call rota (1:6). One local MDT/MDM.*** Main acute elective and non elective inpatient unit in Altnagelvin Approximately 7 elective beds in Causeway(Selected minor/intermediate cases) Day surgery – Altnagelvin, Causeway, Tyrone County Outpatients – Altnagelvin, Causeway, Tyrone County, Roe Valley May wish to consider outreach outpatient and/or day case diagnostics in Mid-Ulster *Mobile ESWL (Lithotripter) on Causeway site
Team South	Lower 1/3rd Western (Fermanagh) and all of Southern integrate to form one Team/Network. Catchment population circa 410,000	Five wte All core Urology Uro-oncology – 2 Stones/endourology – 2* Functional/female Urology – 1	One on-call rota (1:5). One local MDT/MDM.*** Main acute elective and non elective inpatient unit in Craigavon Day surgery – Craigavon, South Tyrone, Daisy Hill Outpatients – Craigavon, South Tyrone, Daisy Hill, Banbridge, Armagh May wish to consider outreach outpatients and/or day case diagnostics in Erne/ Enniskillen *Static/fixed ESWL (lithotripter) on Craigavon site.
Team East	SET + Belfast integrate to form one Team/Network-continue to provide service to patients from Southern sector of Northern Trust (Newtownabbey, Carrickfergus, Larne, ?Antrim). Catchment population circa 870,000 Complex cancer catchment 1.76m	Twelve Wte All core Urology Uro-oncology/cancer centre – 4 Stones/endourology – 3* Functional/female Urology – 2 Reconstruction – 3	One on-call rota (1:12) (may wish to consider 2nd tier on-call). One local MDT/MDM plus regional/specialist MDM.*** Main acute elective and non elective unit in BCH, with elective also in Mater and Ulster Day surgery – BCH, Mater, Lagan Valley, Ards, Downe Outpatients – BCH, Ulster, Mater, Royal, MPH, Ards, Lagan Valley, Downe Should provide outreach outpatient, day case diagnostics and day surgery in Antrim and/or Whiteabbey/Larne *Mobile ESWL lithotripter on BCH site.

Table 14 Elements and Arrangements in Three Team Model

*Population estimates for local District Council areas in Appendix 10. Precise catchment 'lines' on map to be clarified.

** Suggested special interest areas derived from discussions with clinicians and from BAUS guidelines.

*** MDM reconfiguration has been approved by NICaN Group

9.7 In response to concerns expressed at the Steering Group Meeting in January 2009, Speciality Advisor (local and 'Island of Ireland') advice was sought around the issue of a single handed Consultant doing on-call from home covering elective and non elective patients on different sites. The advice has confirmed that such arrangements are possible and that a similar situation exists in other specialties e.g. Trauma and Orthopaedics.

9.8 Urologists have advised that there are very few occasions when a Consultant's presence is required, out of hours, to deal with an elective post operative complication/event. Equally, as described in the previous section of this report, the vast majority of non elective admissions, out of hours, do not require a Consultant's intervention. However, surgeons undertaking elective inpatient surgery on a site other than the main acute unit should use morning lists so as to further ameliorate the impact of out of hour's events. They can minimise the impact further through careful choice of the nature and type of surgery undertaken.

Recommendations

25.	Teams North and East (Northern, Western, Belfast and South Eastern Trusts) should ensure that prior to the creation of the new Teams, there are clear, unambiguous and agreed arrangements in place with regard to Consultant on-call and out of hours arrangements.

26	Each Trust must work in partnership with the other Trust/s within the new team structure to determine and agree the new arrangements for service delivery, including inter alia, governance, employment and contractual arrangements for clinical staff, locations, frequency and prioritisation of outreach services, areas of Consultant specialist interest based on capacity and expertise required and catchment populations to be served.

10. IMPLEMENTATION ISSUES

10.1 To implement the review recommendations a recurrent (full year) investment of £2.875m has been estimated (Appendix 7). Commissioners will need to consider the method of allocating funding to support the full implementation of the recommendations, particularly with regard to aligning the allocation to the additional Consultant distribution profile.

10.2 Trusts and Commissioners will need to take forward discussions with General Practitioners around referral pathways and patient flows in the context of the proposed three team model.

10.3 Trusts will be required to submit detailed business cases prior to funding being released.

10.4 Trusts and Commissioners will need to agree timescales and the measurable outcomes in terms of additional activity, improved performance, a phased reduction in Independent Sector usage and service reform and modernisation plans.

10.5 The implementation of the recommendations of the review may/ will require capital investment to put in place additional physical infrastructure such and to fund equipment associated with technologically driven sub-specialty areas. e.g. endo-urology, reconstruction, laser surgery. Where capital requirements are identified, Trusts should process these bids through their normal capital and business planning cycle.

10.6 The new Teams (Trust partnerships) will be required to submit project plans for implementation of the new arrangements which is envisaged to be on a phased and managed basis. The new Health and Social Care Board will establish an Implementation Board to oversee the process.

GLOSSARY OF TERMS/ABBREVIATIONS

BADS- British Association of Day Surgery

BPH – Benign Prostatic Hyperplasia
A non –cancerous condition in which an overgrowth of *prostate* tissue pushes against the *urethra* and the bladder, restricting or blocking the normal flow of urine. Also known as benign prostatic hypertrophy. This condition is increasingly common in older men.

Biopsy
Removal of a sample of tissue or cells from the body to assist in diagnosis of a disease.

Bladder reconstruction
A surgical procedure to form a storage place for urine following a *cystectomy*. Usually, a piece of bowel is removed and is formed into a balloon-shaped sac, which is stitched to the *ureters* and the top of the urethra. This allows urine to be passed in the usual way.

Brachytherapy
Radiotherapy delivered within an organ such as the prostate.

CNS
Clinical Nurse Specialist

Cystectomy
Surgery to remove all or part of the bladder.

Cystoscope
A thin, lighted instrument used to look inside the bladder and remove tissue samples or small tumours.

Cystoscopy
Examination of the bladder and *urethra* using a *cystoscope*.

ED
Erectile dysfunction

EWTD
European Working Time Directive

Genital
Referring to the external sex or reproductive organs.

Haematuria
The presence of blood in the urine. Macroscopic haematuria is visible to the naked eye, whilst microscopic haematuria is only visible with the aid of a microscope.

HES/Hospital Episode Statistics
HES is the national statistical data warehouse for England of the care provided by NHS hospitals and NHS hospital patients treated elsewhere.

Incontinence
Inability to control the flow of urine from the bladder (urinary) or the escape of stool from the rectum (faecal)

IVP – Intravenous Pyelogram
An x-ray examination of the kidneys, ureters and urinary bladder that uses iodinated contrast material injected into veins.

KUB
Kidney, Ureter, Bladder (Ultrasound)

Laparascopic surgery
Surgery performed using a laparascope; a special type of endoscope inserted through a small incision in the abdominal wall.

LUTS
Lower Urinary Tract Symptoms

MRI - Magnetic resonance imaging
A non-invasive method of imaging which allows the form and metabolism of tissues and organs to be visualised (also known as nuclear magnetic resonance).

MDMs
Mutli-disciplinary meetings

MDTs
Mutli-disciplinary teams

NICaN
Northern Ireland Cancer Network

Oncology
The study of the biology and physical and chemical features of cancers. Also the study of the causes and treatment of cancers.

Prostatectomy
Surgery to remove part, or all of the *prostate gland.* Radical prostatectomy is the removal of the entire *prostate gland* and some of the surrounding tissue.

Prostate gland
A small gland found only in men which surrounds part of the urethra. The prostate produces semen and a protein called *prostate specific antigen (PSA)* which turns the semen into liquid. The gland is surrounded by a sheet of muscle and a fibrous capsule. The growth of prostate cells and the way the prostate gland works is dependent on the male hormone *testosterone*.

PSA – Prostate Specific Antigen
A protein produced by the *prostate gland* which turns semen into liquid. Men with prostate cancer tend to have higher levels of PSA in their blood (although up to 30% of men with prostate cancer have normal PSA levels). However, PSA levels may also be increased by conditions other than cancer and levels tend to increase naturally with age.

Radical treatment
Treatment given with curative, rather than *palliative* intent.

Radiologist
A doctor who specialises in creating and interpreting pictures of areas inside the body. The pictures are produced with x-rays, sound waves, or other types of energy.

Radiotherapy
The use of radiation, usually x-rays or gamma rays, to kill tumour cells. Conventional external beam radiotherapy also affects some normal tissue outside the target area. Conformal radiotherapy aims to reduce the amount of normal tissue that is irradiated by shaping the x-ray beam more precisely. The beam can be altered by placing metal blocks in its path or by using a device called a multi-leaf collimator. This consists of a number of layers of metal sheets which are attached to the radiotherapy machine; each layer can be adjusted to alter the shape and intensity of the beam.

Renal
Of or pertaining to the Kidneys.

Resection
The surgical removal of all or part of an organ.

Scrotum
The external sac that contains the testicles.

Testicle or testis (plural testes)
Egg shaped glands found inside the scrotum which produce sperm and male hormones.

TRUS Tran-rectal ultrasound (TRUS)
An *ultrasound* examination of the prostate using a probe inserted into the rectum.

Trans-uretharal resection (TUR)
Surgery performed with a special instrument inserted through the urethra.

Trans-urethral resection of the prostate (TURP)
Surgery to remove tissue from the prostate using an instrument inserted through the urethra. Used to remove part of the tumour which is blocking the urethra.

Ultrasound
High-frequency sound waves used to create images of structures and organs within the body.

Ureters
Tubes which carry urine from the kidneys to the bladder.

Urethra
The tube leading from the bladder through which urine leaves the body.

Urogenital system
The organs concerned in the production and excretion of urine, together with the organs of reproduction.

Urologist
A doctor who specialises in diseases of the urinary organs in females and urinary and sex organs in males.

Urology
A branch of medicine concerned with the diagnosis and treatment of diseases of the urinary organs in females and the urogenital system in males.

Uro-oncologist
A doctor who specialises in the treatment of cancers of the urinary organs in females and urinary and sex organs in males.

Vasectomy
Surgery to cut or tie off the two tubes that carry sperm out of the *testicles*.

WTE
Whole Time Equivalent

APPENDICES

Appendix 1

Regional Urology Steering Group

Membership

Mr Hugh Mullen (Chair)	SDU, Director of Performance and Provider Development
Mr Mark Fordham	External Advisor, Consultant Urologist
Ms Catherine McNicholl	SDU, Programme Director (Project Manager)
Mr Paul Cunningham	SDU, Performance Manager
Dr Hubert Curran	SDU, Primary Care Advisor
Dr Windsor Murdock	SDU, Primary Care Advisor
Dr Miriam McCarthy	DHSS&PS, Director Secondary Care
Dr Dermot Hughes	NICaN, Medical Director
Mr Patrick Keane	Belfast Trust, Lead Clinician NICaN Urology Group
Dr Diane Corrigan	SHSSB, Consultant Public Health
Dr Janet Little	EHSSB, Acting Director Public Health
Dr Christine McMaster	EHSSB, Specialist Registrar, Public Health
Dr Adrian Mairs	NHSSB, Consultant Public Health
Mr Alan Marsden	NHSSB, Elective Care Commissioning Manager.
Dr Bill McConnell	WHSSB, Director Public Health
Mrs Rosa McCandless	WHSSB, Information Manager
Mrs Karen Hargan	Western Trust, Assistant Director Surgery/Acute Services
Mr Colin Mulholland	Western Trust, Consultant Urologist
Ms Carmel Leonard	Western Trust, Lead Nurse Surgery
Mr Paul Downey	Northern Trust, Consultant Urologist
Mr Martin Sloan	Northern Trust, Director Elective and

	Acute Services
Dr Brian Armstrong	Belfast Trust, Co-Director Specialist Services
Mr Chris Hagan	Belfast Trust, Consultant Urologist
Mr Brian Duggan	Belfast Trust, Consultant Urologist
Mr Brian Best	South Eastern Trust, Consultant Urologist
Mr John McKnight	South Eastern Trust, Consultant Urologist
Mrs Diane Keown	South Eastern Trust, Assistant Director Surgery.
Ms Joy Youart	Southern Trust, Acting Director Acute Services
Mr Michael Young	Southern Trust, Consultant Urologist
Mrs Jenny McMahon	Southern Trust, Nurse Specialist.

Appendix 2

Regional Review of Adult Urology Services

Terms of Reference

Overall Purpose

To develop a modern, fit for purpose in the 21st century, reformed service model for Adult Urology services which takes account of relevant Guidelines (NICE, Good Practice, Royal College, BAUS, BAUN). The future model should ensure quality services are provided in the right place, at the right time by the most appropriate clinician, through the entire pathway from Primary Care to Intermediate to Secondary and Tertiary Care.

It is anticipated that the Review Report will be available for submission to the Department in December 08, subject to Steering Group approval. A multi-disciplinary, key stakeholder Steering Group, chaired by Mr Hugh Mullen will meet to consider and approve the review findings and proposals.

The Review will include the following;

1. Baseline assessment of current service model identifying what is provided where, by whom, performance against access standards and the current profile of investment.

2. Expand on the current capacity/demand modelling exercise to take account of case mix with a view to identifying capacity gaps and informing future investment plans.

3. Develop a service model with agreed patient pathways which informs the distribution of services. The model will also outline proposals for optimising safe, effective and efficient Urology services which meet both access and quality standards/outcomes. The following aspects of the service will be considered;

    - Management of referrals and diagnostics including urodynamics.
    - Development and use of ICATS services
    - Management of acute urological admissions
    - Core Urology (secondary care) Services
    - Andrology Services
    - Interventional Uro-Radiology
    - Endourology/Stone Service
    - Uro-oncology Services
    - Relationship with Uro-gynaecology Services
    - Reconstruction and Neurourology Service
    - Acute Urological management of nephrology patient

4. Make recommendations, as appropriate, on the relationship with the Transplant service and waiting time targets for live donor transplantations.

5. Review workforce planning and training / development needs of the service group and ensure any proposals take account of the need to comply with EWTD (European Working Time Directive.

Appendix 3

UROLOGY REPORTS/ REVIEWS

Northern Ireland Review Reports

Report of the EHSSB Sub Group on Urological Cancer	Sept 1997
Report of the Working Group on Urology Services in Northern Ireland	May 2000
Update on Urology Cancer Services in the EHSSB	Oct 2001
External Review of Urology Services for Craigavon Area Hospital Group	Aug 2004
Draft Service Framework for Cancer Prevention, Treatment and Care – (Urology section)	Version 7 June 2008

National Reports

BAUS – A Quality Urological Service for Patients in the New Millennium	Oct 2000
BAUS – The Provision of Urology Services in the UK	Feb 2002
NICE – (Guidance on Cancer Services) Improving outcomes in Urological Cancers	Sept 2002
Modernisation Agency – Action on Urology – Good Practice Guide	Mar 2005
Providing Care for Patients with Urological Conditions: guidance and resources for commissioners (NHS)	2008
NICE – Urinary Incontinence: the management of urinary incontinence in women	2006
NICE – Prostate Cancer: diagnosis and treatment	2008
NICE – (Urological) Referral guidelines for suspected cancer	2005

Appendix 4

GP REFERRAL EXERCISE - PERCENTAGES

Gender	Belfast	Northern	Western	Southern	SE	Regional Average
Male	77	74	76	79	75	**76**
Female	23	25	22	21	25	**23**
Blank	0	2	2	0	0	**1**
Total	**100**	**100**	**100**	**100**	**100**	**100**
Age Range	**Belfast**	**Northern**	**Western**	**Southern**	**SE**	**Regional Average**
0-14	1	0	0	2	0	**1**
15-30	12	8	11	6	10	**10**
31-40	13	8	11	15	5	**11**
41-50	20	17	9	13	7	**15**
51-60	13	25	20	11	5	**14**
60+	41	42	49	53	12	**38**
Blank	0	2	0	0	60*	**12**
Total	**100**	**100**	**100**	**100**	**100**	**100**
Urgency	**Belfast**	**Northern**	**Western**	**Southern**	**SE**	**Regional Average**
Red Flag	4	4	7	6	5	**5**
Urgent	21	21	22	19	16	**20**
Routine	75	75	71	75	78	**75**
Blank	0	0	0	0	0	**0**
Total	**100**	**100**	**100**	**100**	**100**	**100**
Named Cons	**Belfast**	**Northern**	**Western**	**Southern**	**SE**	**Regional Average**
Y	24	25	13	23	21	22
N	76	75	87	77	79	78
Total	**100**	**100**	**100**	**100**	**100**	**100**
Ref Source	**Belfast**	**Northern**	**Western**	**Southern**	**SE**	**Regional Average**
Non-GP ref's	10	23	2	9	19	**13**
GP Ref's	90	77	96	91	81	**87**
Blank	0	0	2	0	0	**0**
Total	**100**	**100**	**100**	**100**	**100**	**100**

* 44 out of 73 referrals in SET had DOB deleted-therefore not possible to record age range.

Appendix 5

GP REFERRAL EXERCISE – PRESENTING SYMPTOMS (PERCENTAGES)

Presenting Symptom/Condition		Belfast		Northern		Western		Southern		SE		Regional	
Haematuria (ALL)		**13**		**19**		**22**		**9**		**16**		**15**	
	frank		*58*		*30*		*40*		*40*		*50*		*46*
	microscopic		*32*		*50*		*60*		*40*		*50*		*45*
	blank		*11*		*20*		*0*		*20*		*0*		*9*
Prostate/raised PSA		**10**		**13**		**18**		**17**		**16**		**14**	
Other		**15**		**8**		**11**		**15**		**11**		**13**	
Ncode procedure (All)		**15**		**4**		**2**		**6**		**19**		**11**	
	vasectomy		*52*		*0*		*100*		*33*		***29***		***41***
	foreskin		*5*		*0*		*0*		*67*		***50***		***24***
	epididymal cyst		*14*		*100*		*0*		*0*		***21***		***20***
	hydrocele		*19*		*0*		*0*		*0*		***0***		***10***
	varicocele		*5*		*0*		*0*		*0*		***0***		***2***
	blank		*5*		*0*		*0*		*0*		***0***		***2***
Recurrent UTI's		**12**		**17**		**9**		**11**		**5**		**11**	
LUTS		**8**		**13**		**4**		**9**		**10**		**9**	
Prostate/BPH/prostatitis		**8**		**9**		**9**		**11**		**3**		**8**	
Renal stones/colic/loin pain		**8**		**9**		**2**		**4**		**5**		**6**	
Testicular/ Scrotal lumps or swelling		**6**		**0**		**11**		**0**		**11**		**6**	
Andrology (ALL)		**5**		**4**		**7**		**11**		**3**		**5**	
	erectile dysfunction		*29*		*100*		*0*		*50*		*50*		*40*
	peyronie's disease		*29*		*0*		*67*		*0*		*0*		*20*
	blood in ejaculate		*43*		*0*		*0*		*0*		*0*		*15*
	ulcer/lesion on gland		*0*		*0*		*33*		*17*		*0*		*10*
	balanitis/discharge		*0*		*0*		*0*		*33*		*0*		*10*
	blank		*0*		*0*		*0*		*0*		*50*		*5*
Unknown		**2**		**2**		**2**		**4**		**0**		**2**	
Ca Bladder/Kidney		**1**		**2**		**0**		**2**		**0**		**1**	
Blank		**0**		**0**		**2**		**0**		**0**		**0**	
Total		**100**		**100**		**100**		**100**		**100**		**100**	

Appendix 6

NICE – Improving outcomes in Urological Cancers (IOG) – The Manual (2002)

Key Recommendations

The key recommendations highlight the main organisational issues specific to urological cancers that are central to implementing the guidance. As such, they may involve major changes to current practice.

- All patients with Urological cancers should be managed by multidisciplinary Urological cancer teams. These teams should function in the context of dedicated specialist services, with working arrangements and protocols agreed throughout each cancer network. Patients should be specifically assured of:
    - Streamlined services, designed to minimise delays;
    - Balanced information about management options for their condition;
    - Improved management for progressive and recurrent disease.
- Members of Urological cancer teams should have specialised skills appropriate for their roles at each level of the service. Within each network, multidisciplinary teams should be formed in local hospitals (cancer units); at cancer centres, with the possibility in larger networks of additional specialist teams serving populations of at least one million; and at supra-network level to provide specialist management for some male genital cancers.
- Radical surgery for prostate and bladder cancer should be provided by teams typically serving populations of one million or more and carrying out a cumulative total of at least 50 such operations per annum. Whilst these teams are being established, surgeons carrying out small numbers (five or fewer per annum) of either operation should make arrangements within their network to pass this work on to more specialist colleagues.
- Major improvements are required on information and support services for patients and carers. Nurse specialist members of urological cancer teams will have key roles in these services.
- There are many areas of uncertainty about the optimum form of treatment for patients with urological cancers. High-quality research studies should be supported, with encouragement of greater rates of participation in clinical trials.

Appendix 7

Estimated Cost of Implementation of Recommendations.

Staffing	Number	Band/Grade	Unit Cost	Total
Consultant Urologist	6	Consultant	£104,000	£624,000
Consultant Anaesthetist @ 0.6 wte per Con. Urologist	3.6	Consultant	£104,000	£374,400
Consultant Radiologist @ 0.3 wte per Con. Urologist	1.8	Consultant	£104,000	£187,200
Radiographer @ 6 per wte Con Radiologist	10.8	Band 5	£27,995	£302,346
Nursing @ 1.8 wte per Con. Urologist	10.8	Band 5	£27,995	£302,346
Nursing @ 0.46 wte per Con. Urologist	2.7	Band 3	£19,856	£53,611
Specialist Nursing	5	Band 7	£41,442	£207,210
Nursing @ 0.64 wte (day surgery)	0.64	Band 5	£27,995	£17,917
Pers. Secretary @ 0.5 wte per consultant urologists	3	Band 4	£23,265	£69,795
Admin support to radiologists at 0.5 wte per Radiologist	1	Band 3	£19,856	£19,856
Admin Support to Specialist Nurses @ 0.5 wte per Nurse	3	Band 3	£19,856	£59,568
Medical Records support 0.5 per unit	2.5	Band 4	£23,265	£58,162
MLSO – Bio-medical Science	1	Band 7	£41,442	£41,442
Support Costs				
Surgical G&S @ £94,500 per Con. Urologist	X 6		£95,400	£567,000
Theatre Goods/Disposables @ £50,000 per Con.Urologist	X 6		£50,000	£300,000
Radiology G&S per Con. Urologist	X 6		£2,500	£15,000
CSSD @ £32,000 per Con. Urologist	X 6		£32,000	£192,000
Outpatients Clinics @ 2 per Con. Urologist	X 12		£10,000	£120,000
Sub Total				**£3,511,853**
Less Consultant funded in 2008				**(£437,076)**
Sub Total				**£3,074,777**
Less 2008/09 Cancer Funds				**(£200,000)**
FINAL TOTAL				**£2,874,777**

Appendix 8

Evaluation Criteria

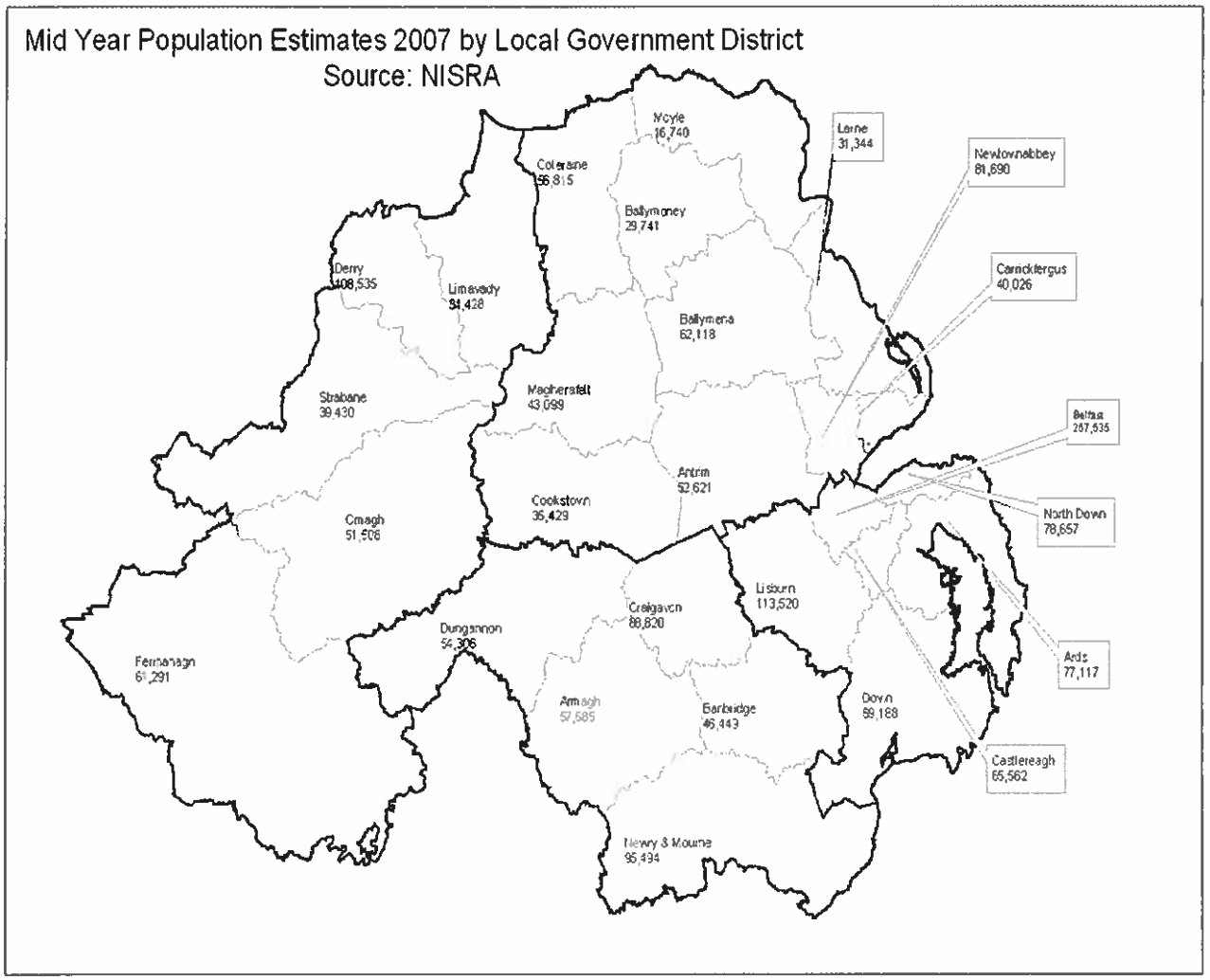
Criteria	Definitions
1. Service Stability / Sustainability	This is the criterion of the highest priority/value. The long term stability and hence viability and success of the service depends on a stable workforce – a workforce that can develop the service further and continue to attract the necessary expertise across all its professions. The criterion is sub-divided into four closely related sub-categories. a. Population – smaller catchment populations restrict the generation of a critical mass of work (cancer and non cancer). Using BAUS recommendations of 1 consultant per 80,000, each team should serve a catchment population of no less than 400,000. b. Team Size – A team of at least five to six consultants is preferred. This will improve long term attractiveness of each team in terms of recruitment and retention. It will also enable at least 2-3 to sub specialise, with dedicated sessions in the sub specialty e.g. uro-oncology, endourology/stones, female urology c. On site interventional radiology and trained urological nursing – These are key quality aspects. On site radiology to ensure timely access to interventions for emergency and urgent cases and sufficient total activity to justify 24 hour urology nursing experience in wards and theatres. This is to enhance multi-disciplinary working and support the development of nurse-led services. d. Commitment to Rotas and Working Time Directive – The service must be capable of sustaining adequate and acceptable on-call arrangements (elective and emergency), compliance with EWTD and equitable provision of emergency care.
2. Feasibility (ease and speed of implementation)	This criterion concerns the need to maximise the use of existing capital infrastructure (beds, theatres, equipment, clinic accommodation). The additional activity required and the appointment of additional Consultants and Nurse Specialists will require additional access to clinical facilities (as described above). It is assumed that the more new capital development is required, the longer the lead in time for starting new teams, and the longer the reliance on the independent sector. Preference will be given to those models that require the least capital resources and restructuring of premises. Consideration of the availability of trained staff will also be given. A particular model will lose points if it is unlikely that trained staff will be available in the numbers required to fill necessary posts.
3. Compliance with DHSSPS Strategy / Commissioner Support / Compatibility with Trust Strategic Plans/impact on other services	A model will lose points if it does not reflect specific regional health and wellbeing strategies/policies – DBS (the location of major hospitals with inpatient care), Cancer Framework (location of cancer units and Cancer Centre). Models should also attract commissioner support. Alignment with Trust Strategic Plans and impact on other services should also be considered.
4. Accessibility for Inpatient Elective Care	It is assumed that each model will be able to facilitate the flexible locating of outpatient and diagnostic service and will therefore be difficult to discriminate scores on this basis. Agreed pathways for emergency care is also assumed. Variation in local provision of elective inpatient care is more discriminatory. A model will lose points if it requires significantly greater travel time (from the do nothing case) for a substantial number of patients.
5. Organisational Complexity	A service should have unambiguous clinical and managerial leadership and accountability arrangements. Some potential models will need to transcend Trust organisational boundaries. This criterion concerns how complicated such arrangements are likely to be and weights each model accordingly – the more complicated the fewer the points awarded.

Appendix 9

Model 3: Three Teams/Networks

Team North and West:	• Upper 2/3rds of Northern and Western integrate to form one Team/Network
	• Main base Hospital - Altnagelvin
	• Potential for small number of inpatient beds in Causeway Hospital to be used for selected elective work subject to satisfactory arrangements for the post-operative management of these patients
Team South and West:	• Lower 1/3rd of Western (Fermanagh) and all of Southern integrate to form one Team/Network
	• Main base Hospital – Craigavon
Team East:	• SET and Belfast integrate to form one Team/Network
	• Continue to provide services to the southern sector of Northern population by outreach – Outpatient/Diagnostics/Day Surgery in Antrim and Whiteabbey hospitals with inpatients going to Belfast

Appendix 10



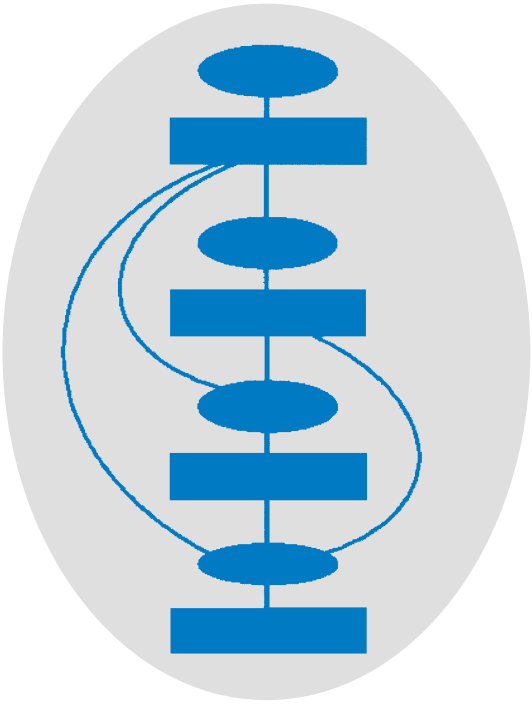
NHS

National Institute for Clinical Excellence

Guidance on Cancer Services

Improving Outcomes in Urological Cancers

The Manual



Urological cancer service guidance

Cancer service guidance supports the implementation of *The NHS Cancer Plan* for England,[1] and the NHS Plan for Wales *Improving Health in Wales.*[2] The service guidance programme was initiated in 1995 to follow on from the Calman and Hine Report, *A Policy Framework for Commissioning Cancer Services.*[3] The focus of the cancer service guidance is to guide the commissioning of services and is therefore different from clinical practice guidelines. Health services in England and Wales have organisational arrangements in place for securing improvements in cancer services and those responsible for their operation should take this guidance into account when planning, commissioning and organising services for cancer patients. The recommendations in the guidance concentrate on aspects of services that are likely to have significant impact on health outcomes. Both the anticipated benefits and the resource implications of implementing the recommendations are considered. This guidance can be used to identify gaps in local provision and to check the appropriateness of existing services.

References

1. Department of Health (2001) *The NHS Cancer Plan.* Available from: www.doh.gov.uk/cancer/cancerplan.htm

2. National Assembly for Wales (2001) *Improving Health in Wales: A Plan for the NHS and its Partners.* Available from: www.wales.gov.uk/healthplanonline/health_plan/content/nhsplan-e.pdf

3. *A Policy Framework for Commissioning Cancer Services*: *A Report by the Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales* (1995). Available from: http://www.doh.gov.uk/cancer/pdfs/calman-hine.pdf

This guidance is written in the following context:

This guidance is a part of the Institute's inherited work programme. It was commissioned by the Department of Health before the Institute was formed in April 1999. The developers have worked with the Institute to ensure that the guidance has been subjected to validation and consultation with stakeholders. The recommendations are based on the research evidence that addresses clinical effectiveness and service delivery. While cost impact has been calculated for the main recommendations, formal cost-effectiveness studies have not been performed.

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Copies of this document can be obtained from the NHS Response Line by telephoning 0870 1555455 and quoting reference N0138. Bilingual information for the public has been published, reference N0139, and a CD with all documentation including the research evidence on which the guidance is based is also available.

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Guidance on Cancer Services

Improving Outcomes in Urological Cancers

The Manual

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Foreword

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Chairman, National Cancer Guidance Steering Group

This is the sixth new title in the series of national guidance documents on the organisation and delivery of cancer services, and the first to be published under the auspices of the National Institute for Clinical Excellence. It deals with a relatively frequent group of cancers, one of which (prostate cancer) has become the subject of increasing patient group and political interest. This is seen by some as a prime men's health issue and it has become a focus for increasing awareness among men of the possibility of cancer.

To those members of the National Cancer Guidance Steering Group who have been in this venture from the beginning, the experience of preparing each successive guidance document has revealed something of a pattern in the way cancer site-specific services develop over time. Familiar issues arise with each cancer site, issues on which the Group has already published recommendations in guidance on services for other cancer sites. It seems that new patterns of practice, adopted by services for one cancer, may not be actively considered by those involved in delivering services for different cancers.

The widely accepted features of modern cancer care were set out in the Calman-Hine report, and those principles have been influential in the most recent statement of national policy in England, the NHS *Cancer Plan*, and in the *Cameron Report* in Wales. Most of the recommendations in Calman-Hine were first applied to breast cancer services, and have subsequently been adapted in developing services for other common cancers such as colorectal and lung.

Whilst there are honourable exceptions, urological cancer services in general have lagged behind in adopting these principles, although there are encouraging signs that this has begun to change. For example, properly constituted multidisciplinary clinical teams (MDTs) are less common in urology than in some other areas. In both surgery and non-surgical oncology for urological malignancies, care is often fragmented, with most individuals handling cases outside formal MDTs. This guidance provides the impetus to change this state of affairs.

So what are these predictable common themes? The first can best be described as an 'awakening': a growing recognition, often expressed by patient groups as well as influential professionals in the field

concerned, of the variability and deficiencies in current organisation and delivery of clinical care to patients. Awareness that the delivery of services needs to become more consistent and coherent opens the way to change.

The second is the crucial importance of the diagnostic and referral process. Reliable and thorough diagnosis is the cornerstone of good clinical cancer care. Optimum decisions on management depend on the accurate, reliable, and comprehensive diagnosis and staging of disease. Without all the relevant information, of a quality that can be relied on, those involved in decisions on clinical management are disadvantaged, as are their patients. Important weaknesses have been found in urological cancer diagnostics - as there were in diagnostic services for breast and other common cancers. Site-specific cancer services need the involvement of diagnostic specialists working carefully to modern protocols. Improvements in services for specific cancers require diagnostic specialisation and professional continuity, with the full involvement of these individuals in multidisciplinary working. Urological malignancies are no exception. Putting this emphasis on the importance of the diagnostic contribution is justifiable notwithstanding an acknowledged and serious shortfall in the supply of qualified individuals in the relevant disciplines. Addressing this will inevitably take time, but it remains a critical objective.

The next recurring theme is the way in which decisions on the management of individual patients are best taken. Multidisciplinary teams which involve all the different professions and disciplines required for each group of cancers need to be assembled. Getting these teams to work together effectively, and supporting their activities, is the key to doing this well. The skills of all the members are important to clinical decision-making, which then becomes a collective process.

Another common strand is the importance of defining the natural sequence of events in the organisation and delivery of care. The processes from first referral through to arrangements to manage recurrent and advanced disease have to reflect the needs of the patient at various stages. This is a major driver to shape the way services are organised and delivered. Such ideas are not by any means the sole province of this guidance. There has been huge interest in defining pathways of care and thinking through patient journeys. The Cancer Services Collaborative in England has encouraged fresh thinking on many of the logistic and organisational issues which professionals face in delivering care to their patients.

The final theme that occurs remorselessly is the need to determine whether there are any aspects of service - often, but not exclusively, dealing with rare forms of disease or complex procedures - which would be best provided for larger populations and caseloads than can

be managed by local services. This has proved to be a crucial factor in shaping the service pattern for cancers of intermediate frequency. There are inevitably vested interests amongst the clinical communities concerned, and sometimes tensions between those who favour one model or another. Whilst evidence on these matters is not always profuse, it does exist, and has to be carefully considered for each group of cancers. We have been struck by the consistency between results of studies on different cancers.

The evidence base for managing urological malignancies is less comprehensive and in some important clinical areas, less clear, than for many other cancers. This has made the task of reviewing evidence particularly difficult. It is an appropriate point to gratefully acknowledge the huge contribution made by external reviewers to these guidance documents.

A new and important feature of the implementation process is the recent advent of National Cancer Standards in England and the Minimum Standards for Cancer Services in Wales. Key features of each guidance document will be incorporated in future revisions of these standards, expanding the range of the accompanying peer reviews. Implementation is the prime function of cancer networks, too, supported by the rollout of the Cancer Services Collaborative in England. This Guidance uses the results from some Collaborative projects as evidence; it is the first time this has been available to us.

Taken together, the service context for implementing guidance has advanced very considerably since the early years following publication of Calman-Hine. There is now systematic support for the implementation of the *Cancer Plan* in England and the *Cameron Report* in Wales, of which this guidance is only one element. Together these will help to realise one of the original goals of Calman-Hine, which was (and remains) arguably the single most crucial objective:-

> ***'All patients should have access to a uniformly high quality of care in the community or hospital wherever they may live to ensure the maximum possible cure rates and best quality of life. Care should be provided as close to the patient's home as is compatible with high quality, safe and effective treatment'.***

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Key recommendations

The key recommendations highlight the main organisational issues specific to urological cancers that are central to implementing the guidance. As such, they may involve major changes to current practice.

- All patients with urological cancers should be managed by multidisciplinary urological cancer teams. These teams should function in the context of dedicated specialist services, with working arrangements and protocols agreed throughout each cancer network. Patients should be specifically assured of:
  - Streamlined services, designed to minimise delays;
  - Balanced information about management options for their condition;
  - Improved management for progressive and recurrent disease.
- Members of urological cancer teams should have specialised skills appropriate for their roles at each level of the service. Within each network, multidisciplinary teams should be formed in local hospitals (cancer units); at cancer centres, with the possibility in larger networks of additional specialist teams serving populations of at least one million; and at supra-network level to provide specialist management for some male genital cancers.
- Radical surgery for prostate and bladder cancer should be provided by teams typically serving populations of one million or more and carrying out a cumulative total of at least 50 such operations per annum. Whilst these teams are being established, surgeons carrying out small numbers (five or fewer per annum) of either operation should make arrangements within their network to pass this work on to more specialised colleagues.
- Major improvements are required in information and support services for patients and carers. Nurse specialist members of urological cancer teams will have key roles in these services.
- There are many areas of uncertainty about the optimum form of treatment for patients with urological cancers. High-quality research studies should be supported, with encouragement of greater rates of participation in clinical trials.

Background

Incidence and mortality

The group of diseases with which this Manual deals – cancers of the prostate, testis, penis, kidney and bladder – account for 16.5% of all new cases of cancer (excluding non-melanoma skin cancer) and 11.7% of cancer deaths.[1,2] Prostate cancer is the second most frequently diagnosed cancer among men of all ages; testicular cancer, although relatively infrequent, is nevertheless the most common cancer in men under 45 years of age. Cancer of the penis, by contrast, is rare. Cancers of the kidney and bladder may develop in people of either sex but are roughly twice as common among men (Table 1). Numbers of deaths and mortality rates are shown in Table 2.

Table 1. Urological cancers and cancers of the male genital system: registrations and incidence, 1998, England and Wales

Cancer site	ICD10 code	England			Wales		
		Registrations	Incidence: rate per 100,000		Registrations	Incidence: rate per 100,000	
		Total	Men	Women	Total	Men	Women
Prostate	C61	19,335	79.3	-	1,264	87.9	-
Penis	C60	315	1.3	-	23	1.6	-
Kidney	C64-66	4,653	11.8	6.8	327	12.9	9.5

Source: Data for England downloaded from www.statistics.gov.uk, May 2002; data for Wales provided on request by the Welsh Cancer Intelligence & Surveillance Unit, Cardiff, May 2002.

1 Office for National Statistics. *Mortality statistics - cause, England and Wales, 1999.* London: Stationery Office, 2000.

2 Office for National Statistics. *Cancer statistics - registrations, England, 1995-1997.* London: Stationery Office, 2001.

Table 2. Urological cancers and cancers of the male genital system: number of deaths and mortality rates, 2000, England and Wales

Cancer site	ICD10 code	England			Wales		
		Deaths	Mortality: crude rate per 100,000		Deaths	Mortality: crude rate per 100,000	
		Total	Men	Women	Total	Men	Women
Prostate	C61	7,785	31.5	-	492	34.0	-
Testis	C62	63	0.3	-	6	0.4	-
Penis	C60	83	0.3	-	12	0.8	-
Bladder	C67	4,173	11.0	5.7	152	10.5	5.6
Kidney	C64-66	2,548	6.3	3.9	92	6.4	4.8

Source: Data provided on request by the Office of National Statistics, London, and the Welsh Cancer Intelligence & Surveillance Unit, Cardiff, May 2002.

Considered as a group, these cancers are slightly more common in the population as a whole than breast cancer (37,000 new cases of urological and male genital cancers, 33,350 of breast cancer in 1997; both sexes, England and Wales). But whilst it may be useful for service planning to lump together all the cancers considered in this Manual, the patterns of care required for each cancer site vary widely because these cancers are very different in nature and characteristics.

Prostate cancer is particularly common among elderly men; two thirds of those who die from prostate cancer are over the age of 75.[3] Autopsy studies reveal that the majority of men over 80 years old have areas of malignant tissue in their prostate glands; most die *with* it, not *of* it.[4] Prostate cancer may be identified as a result of investigations or intervention for symptoms related to benign prostate disease, also a very common condition in elderly men. However, when prostate cancer develops in younger men, it seems to have a more aggressive nature. Relatively few of the 40-49 age-group are affected, but these men have the highest mortality rate.[3]

[3] Quinn M, Babb P, Brock A, *et al. Cancer trends in England and Wales 1950-1999.* London: Stationery Office, 2001.

[4] Selley S, Donovan J, Faulkner A, *et al.* Diagnosis, management and screening of early localised prostate cancer. *Health Technol Assess* 1997;**1**.

Testicular cancer is very different. It is predominantly found in young men, with a modal age at diagnosis of about 30.[5] It may be associated with developmental abnormalities of the urogenital system.

Cancers of the kidney, bladder and associated urinary organs are neither especially common nor rare. They are most likely to occur in men aged between 60 and 80 years. Penis cancer tends to affect the same age-group.[2]

In a single year, the average GP, with a list of 2,000 patients, is likely to see one or two new patients with one of these cancers per year. A notional average district general hospital (DGH), serving a population of 200,000, deals with roughly 70 men with prostate cancer, 6 with testicular cancer, perhaps 20 people with kidney and 50 with bladder cancer – a total of around 150 new patients per year with urological cancers. Figures for prostate cancer incidence show particularly wide geographical variations because more cases are identified when patients and clinicians search more aggressively for it.

Five-year survival rates are shown in Table 3. Although there has been little overall change in these rates between patient groups diagnosed in 1986-90 and 1991-93, the significant improvement for men with testicular cancer – a rise in five-year survival rates from 91.2% to 94.5% – is notable in view of the small amount of room for such improvement. The 7% improvement in prostate cancer survival rates is, however, likely to be due more to lead time and length time biases associated with increasing use of prostate specific antigen (PSA) testing than to improvements in treatment.[2]

[5] United Kingdom Testicular Cancer Study Group. Aetiology of testicular cancer: association with congenital abnormalities, age at puberty, infertility and exercise. *BMJ* 1994;**308**:1393-9.

Table 3. Urological cancers and cancers of the male genital system: five-year relative survival rates (age-standardised), England and Wales[*2]

Cancer site	ICD10 code	Five-year survival rates by year of diagnosis					
		1986-90		1991-3		1993-5[a]	
		Men	Women	Men	Women	Men	Women
Prostate	C61	42.2	-	48.9	-	54.9	-
Testis	C62	91.2	-	94.5	-	N/A	-
Penis	C60	69.0	-	63.1[b]	-	N/A	-
Bladder	C67	65.2	57.9	65.7	57.6	66.2	57.9
Kidney	C64-66	39.6	35.6	40.5	37.3	N/A	N/A

* All stages of disease are combined in tables 1-3; thus bladder cancer, for example, includes both superficial and invasive tumours.

[a] England only; data downloaded from ONS online, May 2002.

[b] Northern, Yorkshire and Humberside only; data from the Northern and Yorkshire Cancer Registry and Information Service.

For testicular and bladder cancers, age-standardised survival rates in England are similar to the European average, but for cancers of the kidney and prostate, survival rates in England are significantly lower than in many European countries (Table 4).[6] This evidence is not, however, sufficient to determine the cause or importance of these differences. It is possible that they are associated with earlier diagnosis in some parts of Europe, where greater use of imaging will tend to increase the rate of detection of small (incidental) kidney tumours and widespread PSA testing will reveal more early prostate cancers. The apparent survival differences could therefore be due, at least in part, to length and lead-time biases.

[6] Berrino F, Sant M, Verdecchia A, *et al. Survival of cancer patients in Europe: the EUROCARE study.* Lyon: International Agency for Research on Cancer, 1995.

Table 4. Urological cancers and cancers of the male genital system: five-year relative survival rates (age-standardised), England and Europe, 1985-9.[6]

Cancer site	Five-year survival rates, % England		Five-year survival rates, % (95% CI) European average	
	Men	Women	Men	Women
Prostate	44.3	-	55.7 (54.3-57.1)	-
Testis	90.0	-	89.5 (87.4-91.7)	-
Penis	70.2	-	73.7 (67.6-80.4)	-
Bladder	65.6	59.4	65.2 (63.8-66.6)	59.7 (57.5-61.9)
Kidney	39.4	36.9	47.7 (45.6-49.9)	49.8 (47.1-51.6)

Symptoms and presentation

Most patients with urological cancers are referred to urologists by their GPs. Some present with symptoms such as bone pain, which may not be immediately recognised as due to metastatic urological cancer, and some are referred by geriatricians.

The main presenting symptoms of primary urological tumours fall into three groups: lower urinary tract symptoms, haematuria, and suspicious lumps. Lower urinary tract symptoms are relatively common. In older men, they are often due to benign prostatic hyperplasia, which is at least four times as common as prostate cancer and may co-exist with it.[4,7] Cancer is very unlikely to be the cause of such symptoms in younger men or women, but persistent problems that fail to respond to antibiotics are occasionally due to bladder cancer.

Haematuria, or blood in the urine, is the most common symptom of both bladder and kidney cancer. Around one patient in five who develops visible haematuria is likely to have urological – usually bladder – cancer.[8,9] Whilst population studies suggest that

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7 Chamberlain J, Melia J, Moss S, *et al*. Report prepared for the Health Technology Assessment panel of the NHS Executive on the diagnosis, management, treatment and costs of prostate cancer in England and Wales. *BJU Int* 1997;**79 (Suppl 3)**:1-32.

8 Buntinx F, Wauters H. The diagnostic value of macroscopic haematuria in diagnosing urological cancers: a meta-analysis. *Fam Pract* 1997;**14**:63-8.

9 Lynch TH, Waymont B, Dunn JA, *et al*. Rapid diagnostic service for patients with haematuria. *Br J Urol* 1994;**73**:147-51.

microscopic haematuria, on its own, rarely signifies malignant disease,[10,11] studies carried out in hospital haematuria clinics tend to find higher cancer rates among patients with microscopic haematuria;[12] this difference could reflect other, unmeasured, criteria which GPs consider when they make the decision to refer.

Whilst the most common presenting symptom of kidney cancer is haematuria, this disease is often asymptomatic until it reaches a late stage. It is diagnosed increasingly frequently when imaging, carried out for some other reason, reveals a mass in the kidney. A recent (unpublished) audit in north west England reported that in 37% of patients with kidney cancer, the tumour was an incidental finding.[13]

Most patients with testicular cancers present with a lump in the scrotum, usually detected initially by the man himself or by his partner.

Epidemiology, trends and treatment

Prostate cancer

Registration and mortality rates for prostate cancer have been increasing (Figure 1), although how great the true increase in incidence may be is not clear because early, asymptomatic disease is more likely to be diagnosed than in previous decades. The main reason for this is the use of PSA testing, which became commonplace during the last decade. Despite this, about a quarter of patients in the UK have advanced disease at the time of diagnosis (Table 5); in these cases, bone pain caused by metastatic cancer may prompt the initial consultation.

Both diagnosis and mortality rates began to fall again after 1995 (see Figure 1). Current trends in diagnosis rates are unclear, but even if these do not rise, the ageing of the population means that the number of men with prostate cancer can be expected to increase to around 22,000 by 2011 (figures extrapolated from Chamberlain *et al*, 1997[7]). The scale of the problem and increasing public concern has led to the initiation of a range of measures such as the NHS Prostate

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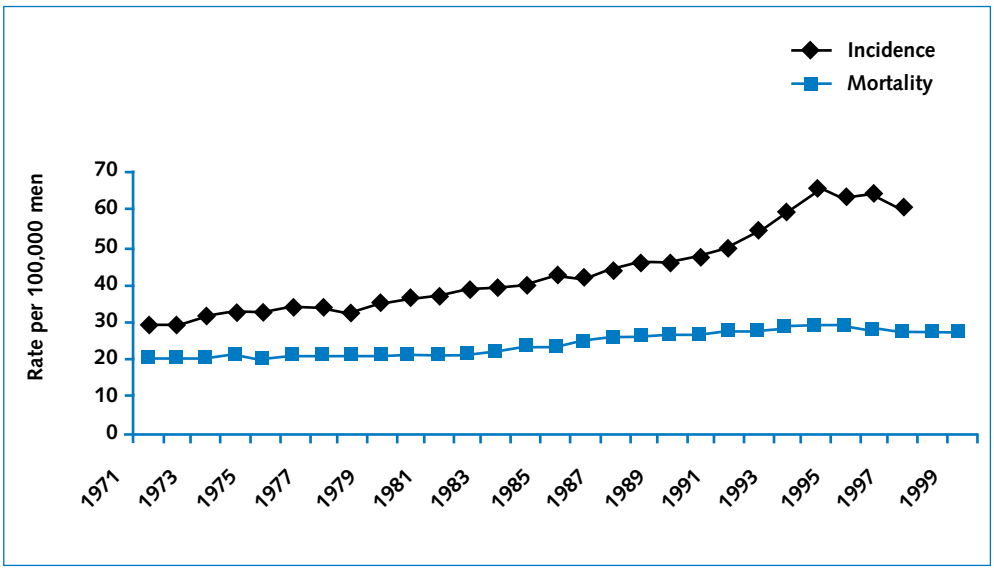
[10] Froom P, Froom J, Ribak J. Asymptomatic microscopic hematuria - is investigation necessary. *J Clin Epidemiol* 1997;**50**:1197-200.

[11] Froom P, Ribak J, Benbassat J. Significance of microhaematuria in young adults. *BMJ* 1984;**288**:20-2.

[12] Khadra M, Pickard M, Charlton P. A prospective analysis of 1,930 patients with hematuria to evaluate current diagnostic practice. *J Urol* 2000;**163**:524-7.

[13] Clarke N. Personal communication. 2001.

Figure 1. Prostate cancer: incidence and mortality rates (age-standardised), England and Wales, 1971-1999



Source: Data provided on request by the Office of National Statistics, London

Table 5. Prostate cancer: stage at diagnosis

Clinical stage[a]	Classification	Description	Proportion of new cases
Organ-confined (Stage I or II)	T1 or T2, N0 M0	Cancer confined to prostate	52%
Extra-capsular (Stage III)	T3 N0 M0	Tumour extends through prostate capsule	26%
Locally advanced (Stage IV)	T4 N0 M0 Any T, N≥1	Tumour in lymph nodes or tissues close to prostate	22%
Metastatic (Stage IV)	Any T, M≥1	Metastatic disease, usually in bones	

Source: Figures derived from British Association of Urological Surgeons (BAUS) data for 1999. This database includes about 60% of cases and may not accurately reflect the population as a whole.

[a] Clinical staging is used in decision-making about management but this is not always clearly related to pathological staging.

Cancer Programme and a Prostate Cancer Risk Management Programme. One recent change to policy was the decision that PSA tests should be available to men who request them, but that they should first be provided with clear information about the test and the uncertainty about the balance of benefits and risks of screening for prostate cancer. This information is now available on the National electronic Library for Prostate Cancer.[14]

Neither the causes of prostate cancer nor the reasons for the increase in mortality rate over the past thirty years are known, although some risk factors have been identified. Hormones are important; meta-analysis of cohort and case-control studies show that men with serum testosterone levels in the highest quartile are 2.3 (95% CI: 1.3 to 4.2) times as likely to develop prostate cancer as those in the lowest quartile. High levels of insulin-like growth factor (IGF-1) are associated with a similar increase in risk.[15]

Genetic factors are important in about 9% of cases, particularly when the disease develops at a young age. The risk is doubled when a man has one close relative with this cancer and it increases with the number of relatives affected.[16] Increased risk has also been linked with a family history of breast cancer.

A suggested association between vasectomy and prostate cancer was not confirmed by a thorough systematic review and meta-analysis of research evidence.[17]

There are wide international variations in the incidence of clinically-evident prostate cancer. The highest rates – over 100 per 100,000 – are found among African-Americans, and the lowest among Asians, with fewer than 10 men per 100,000 affected. European men fall into an intermediate position.[18]

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[14] See http://www.nelh.nhs.uk/psatesting

[15] Shaneyfelt T, Husein R, Bubley G, *et al*. Hormonal predictors of prostate cancer: A meta-analysis. *J Clin Oncol* 2000;**18**:847-53.

[16] McLellan DL, Norman RW. Hereditary aspects of prostate cancer. *Can Med Assoc J* 1995;**153**:895 900.

[17] Bernal-Delgado E, Latour-Perez J, Pradas-Arnal F, *et al*. The association between vasectomy and prostate cancer: a systematic review of the literature. *Fertil Steril* 1998;**70**:191-200.

[18] Dijkman GA, Debruyne FM. Epidemiology of prostate cancer. *Eur Urol* 1996;**30**:281-95.

One reason for this variation between ethnic groups is likely to be differences in diet, and a variety of relationships have been found between prostate cancer risk and specific types of food. Decreased risk is associated with a high intake of vegetables rich in carotenoids, particularly tomatoes.[18,19,20,21] Fish also seems to be protective.[22]

Increased risk is associated with diets high in animal fat;[19] this might be linked with bio-concentration in animal fat of agricultural chemicals which affect hormone levels.[23] Evidence that high consumption of dairy products can double the risk of prostate cancer (especially advanced disease), even after controlling for fat intake, has led to the development of a yet another hypothesis: that high calcium intake may promote these tumours.[24] The true reasons for the higher risk associated with dietary patterns of northern Europe, North America and Australasia remain unknown.

Prostate cancer may be detected by PSA testing, digital rectal examination (DRE), and trans-rectal ultrasound (TRUS) guided biopsy. Tumour may also be found by pathological examination of tissue samples after trans-urethral resection of the prostrate (TURP) carried out to relieve urinary obstruction.

The disease usually progresses slowly, but prognosis depends heavily on the grade of the tumour. This is assessed using the Gleason scoring system. Gleason scores range from 2 to 10; more aggressive cancers, which spread faster beyond the prostate, have higher scores. Audit data from north west England (unpublished) suggests that two-thirds of new patients have moderately differentiated tumours, with Gleason scores of 5 to 7; the remainder are roughly equally divided between the lower and higher ranges of the scale.[13] The Gleason score is used in combination with PSA level and information on local tumour spread gained from DRE and TRUS to assess prognosis.

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[19] World Cancer Research Fund. *Food, nutrition and the prevention of cancer: a global perspective*. Washington DC: American Institute for Cancer Research, 1997.

[20] Cohen J, Kristal A, Stanford J. Fruit and vegetable intakes and prostate cancer risk. *J Natl Cancer Inst* 2000;**92**:61-8.

[21] Giovannucci E. Tomatoes, tomato-based products, lycopene, and cancer: Review of the epidemiologic literature. *J Natl Cancer Inst* 1999;**91**:317-31.

[22] Terry P, Lichtenstein P, Feychting M, *et al*. Fatty fish consumption and risk of prostate cancer. *Lancet* 2001;**357**:1764-6.

[23] Kellerbyrne JE, Khuder SA, Schaub EA. Meta-analyses of prostate cancer and farming. *Am J Ind Med* 1997;**31**:580-6.

[24] Chan J, Giovannucci E, Andersson S, *et al*. Dairy products, calcium, phosphorus, vitamin D, and risk of prostate cancer. *Cancer Causes Control* 1998;**9**:559-66.

Data from a large US study suggest that 10-year disease-specific survival rates are over 90% among men with early, low grade tumours, and over 75% among those with intermediate grade tumours, whatever form of treatment is used.[25] Death-rates are, as would be expected, higher among patients with higher grade tumours.

Approaches to treatment range from active monitoring and conservative treatment of symptoms (also known as "watchful waiting") to radical surgery (prostatectomy), radical radiotherapy (external beam or implantation of radioactive seeds – brachytherapy) and hormone treatment. Radical treatment is associated with significant complications, particularly impotence and incontinence; and whilst it can control local symptoms, there is no clear evidence showing whether it improves survival. Hormone treatment reduces the rate of progression of the cancer and may be used in combination with other forms of treatment or as the primary intervention; however, it also causes loss of libido and impotence. Active monitoring is particularly appropriate for men whose tumours are not expected to cause problems in their lifetime, either because their life-expectancy is relatively short or because the cancer is small and growing only slowly.[4]

The main problems in advanced prostate cancer are lower urinary tract symptoms and pain due to metastatic disease, predominantly in bones. Palliative interventions include hormone treatment, radiotherapy and analgesia.

Testicular cancer

There has been a continuous rise in the incidence of testicular cancer over the past few decades. A large case-control study in England and Wales has elucidated some aspects of the aetiology of this disease; it revealed significant associations with congenital abnormalities, particularly undescended testes, early age at puberty, and sedentary lifestyle.[5] The incidence of undescended testes – linked with a four-fold increase in risk (odds ratio 3.82, 95% CI: 2.24 to 6.52) – has also been increasing. Family members of men with testicular cancer are at increased risk; the probability that a brother of an affected man will develop the disease by the age of 50 is around 2% - 10 times the general population risk.[26] The majority of cases are identified at an early stage, however, (Table 6) and this form of cancer can usually be cured even when it has spread beyond the testis.

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[25] Lu-Yao G, Yao S. Population based study of long term survival in patients with clinically localised prostate cancer. *Lancet* 1997;**349**:906-10.

[26] Forman D, Oliver RT, Brett AR, *et al*. Familial testicular cancer: a report of the UK family register, estimation of risk and an HLA class 1 sib-pair analysis. *Br J Cancer* 1992;**65**:255-62.

There is a widespread belief among health professionals that young men should be educated to examine their testes for lumps in order that any cancer might be treated as quickly as possible. But young men are notoriously disinterested in health. Few examine themselves even after specific teaching, and there is no evidence that educational interventions intended to encourage them to do so are effective.[27]

There are two main types of testicular tumour, seminoma and non-seminoma. Surgery is used to treat both types and may be sufficient to control the disease, but patients with seminoma may be treated with post-operative radiotherapy, whilst chemotherapy is more appropriate for patients with non-seminomas. Success rates are high – fewer than 10% of patients die from testicular cancer – but the problem may recur: up to 5% of men develop cancer in the remaining testis within 25 years of the initial diagnosis.[28]

Table 6. Testicular cancer: stage at diagnosis (1980-94)

Clinical stage (Royal Marsden Stage)	Proportion of new cases
Early (stage I)	55%
Lymph node metastases (stage II – III)	28%
Distant metastases (stage IV)	17%

Source: Figures derived from data on 1,600 patients from The Royal Marsden Hospital Testicular Tumour Unit, 1980-1994.

Penile cancer

Penile cancer is rare in developed countries, particularly in men who were circumcised as babies, and there have been few reliable studies of risk factors or potential causes. However, there is accumulating evidence suggesting that infection with human papillomavirus (HPV or genital warts) may be involved in many cases.[29] A North American case-control study found that the risk for men with a history of such infection was six times that in age-matched controls, and that 49% of tumours contained HPV genetic material.[30] Other factors which increased risk three-fold or more were smoking; lack of, or late, circumcision; and a history of penile rash or tear.

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[27] Rosella JD. Testicular cancer health education: an integrative review. *J Adv Nurs* 1994;**20**:666-71.

[28] Colls BM, Harvey VJ, Skelton L, *et al*. Bilateral germ cell testicular tumors in New Zealand: experience in Auckland and Christchurch 1978-1994. *J Clin Oncol* 1996;**14**:2061-5.

[29] Holly EP, Palefsky JM. Factors related to risk of penile cancer. *J Natl Cancer Inst* 1993;**85**:2-3.

[30] Maden C, Sherman KJ, Beckmann AM, *et al*. History of circumcision, medical conditions, and sexual activity and risk of penile cancer. *J Natl Cancer Inst* 1993;**85**:19-24.

These cancers tend to be fairly obvious and can be diagnosed before the tumour has progressed to an advanced stage, so survival rates are fairly high (around 65-70% at five years). Usually, there is a painless ulcer or growth, most often on the glans or foreskin, but some men develop a rash, bumps or flat growths on the penis and there may be foul-smelling discharge under the foreskin. Diagnosis is by biopsy. The most common treatment is surgery but radiotherapy may be an option. Topical chemotherapy or laser treatment can be used for superficial tumours (carcinoma in situ). Radiotherapy or systemic chemotherapy can be used for palliation in metastatic disease.

Bladder cancer

The most common causes of bladder cancer are carcinogenic chemicals – particularly aromatic amines – in urine. An important source of such carcinogens is cigarette smoke, and there is a significant dose-response relationship between the lifetime number of cigarettes smoked and the risk of bladder cancer. Meta-analysis of data from 43 studies reveals that, compared with non-smokers, current smokers face three times the risk of developing urinary tract cancers (odds ratio 3.33; 95% CI: 2.63 to 4.21), whilst for ex-smokers, the risk is doubled (odds ratio 1.98; 95% CI: 1.72 to 2.29).[31] Current cigarette smokers are two to five times more likely to develop bladder cancer than non-smokers, the level of risk increasing among heavier smokers; but quitting leads to a 30-60% fall in risk within four years.[32,33] Since rates of smoking have been falling faster among men than women, it is possible that the difference between the sexes in bladder cancer rates could decrease, as with lung cancer.

Up to 20% of bladder cancers may be caused by exposure to chemicals in the workplace.[34] These can cause bladder cancer five to 50 (typically, 10-15) years later. The highest risk is again associated with aromatic amines, which used to be commonplace in dyes, paints and plastics and are currently found in diesel exhaust fumes and other industrial by-products.

Occupations associated with increased risk include work in textile, dyestuffs, chemical or plastics industries; tyre and rubber manufacture; truck and taxi driving; painting and printing; metalwork; work in the cable industry; leather work and hairdressing.[32,34]

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[31] Zeegers M, Tan F, Dorant E, *et al*. The impact of characteristics of cigarette smoking on urinary tract cancer risk: a meta-analysis of epidemiologic studies. *Cancer* 2000;**89**:630-9.

[32] Silverman DT, Hartge P, Morrison AS, *et al*. Epidemiology of bladder cancer. *Hematol Oncol Clin North Am* 1992;**6**:1-30.

[33] Hartge P, Silverman D, Hoover R, *et al*. Changing cigarette habits and bladder cancer risk: a case-control study. *J Natl Cancer Inst* 1987;**78**:1119-25.

[34] Vineis P, Simonato L. Proportion of lung and bladder cancers in males resulting from occupation: a systematic approach. *Arch Environ Health* 1991;**46**:6-15.

Bladder cancer in places such as Egypt is often associated with infection with the water-borne parasite *Schistosoma* (bilharzia). Other causes include previous treatment for cancer – in particular, radiotherapy to the pelvis and some forms of chemotherapy. Long-term use of chlorinated drinking water may increase the risk up to two-fold.[32]

95% of patients present with haematuria and cancer can be detected using a cystoscope to view the inside of the bladder. The staging system for bladder cancer is summarised in Table 7.

In about three quarters of new cases, the cancers are superficial and can be removed by surgery carried out through the urethra (trans-urethral resection, or TUR). Irrigation of the bladder with immunotherapeutic or chemotherapeutic agents may be used to reduce the probability of recurrence of superficial cancers. Surgery, radiotherapy and, increasingly, chemotherapy, are used to treat invasive tumours. Metastatic disease may be widespread, affecting lymph nodes, liver, lungs and bones.

Table 7. Bladder cancer: stage at diagnosis

Clinical stage	Classification	Description	Proportion of new cases
Lower-risk superficial cancer	PTa G1 or G2	Non-invasive tumours	45%
	pT1 G1 pT1 G2	Low-grade invasive tumours, no muscle invasion; G2 tumours are more likely to progress than G1	
High-risk superficial cancer	PTa G3 or pT1 G3	High-grade tumours, no muscle invasion; likely to recur and progress	23%
Muscle invasive	pT2	Tumour in muscular wall of bladder	18%
Locally advanced	pT3	Tumour in perivesical fat	9%
	pT4	Tumour in pelvic organs	5%
Metastatic	M	Tumour in distant tissues such as bones	

Source: Figures derived from British Association of Urological Surgeons (BAUS) data for 1999.[35] This database may not accurately reflect the population as a whole.

[35] British Association of Urological Surgeons: Section of Oncology. *Analyses of minimum data set for Urological cancers, January 1st to December 31st, 1999.* British Association of Urological Surgeons, 2000. Available from: http://www.baus.org.uk

Kidney cancer

Kidney cancer is less common than bladder or prostate cancer (Table 1) although both incidence and mortality rates are rising steadily in developed countries. The most common form is renal cell cancer, which accounts for over 80% of cases in England and Wales. The other main form of kidney cancer (transitional cell carcinoma) affects the renal pelvis; similar tumours can also develop in the ureters. Where this Manual refers to kidney cancer without further specification, it should be assumed to mean renal cell cancer.

Over two decades from the mid-1970s to the mid-1990s, the incidence of renal cell cancer rose by about 3% per annum in the US[36] and 2.5% per annum in northern England.[37] The English data show an 86% age-standardised increase between 1978 and 1997. Whilst part of this rise is likely to be due to increased detection of early, pre-symptomatic tumours by imaging, this does not account for much of the change in incidence.

A quarter of kidney cancers are believed to be directly attributable to smoking; smokers are more than twice as likely to develop renal cell cancer and four times as likely to develop cancer of the renal pelvis as non-smokers.[38] Renal cell cancer is more common in obese people, and is independently associated with hypertension.[39] In Minnesota, these three risk factors together account for half of all cases.[40] Whilst there are other known risk factors, such as exposure to cadmium and the once-popular analgesic phenacetin,[38,41] their impact on kidney cancer incidence in the population as a whole is much less than that of obesity, hypertension and smoking.

Some kidney cancers are due to genetic influences. Two rare conditions associated with specific mutations are von Hippel-Lindau syndrome, which increases the risk of kidney and other cancers, and Wilms' Tumour, which affects children. In addition, a family history of renal cell cancer is associated with increased risk.

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[36] Chow WH, Devesa SS, Warren JL, *et al*. Rising incidence of renal cell cancer in the United States. *JAMA* 1999;**281**:1628-31.

[37] Tate R, *et al.* Increased Incidence of Renal Parenchymal Carcinoma in the Northern and Yorkshire region of England, 1978-1997. (submitted for publication).

[38] McCredie M, Stewart JH. Risk factors for kidney cancer in New South Wales. *Br J Ind Me* 1993;**50**:349-54.

[39] McLaughlin JK, Mandel JS, Blot WJ, *et al*. A population-based case-control study of renal cell carcinoma. *J Natl Cancer Inst* 1984;**72**:275-84.

[40] Benichou J, Chow W, McLaughlin J, *et al*. Population attributable risk of renal cell cancer in Minnesota. *Am J Epidemiol* 1998;**148**:424-30.

[41] Sali D, Boffetta P. Kidney cancer and occupational exposure to asbestos: a meta-analysis of occupational cohort studies. *Cancer Causes Control* 2000;**11**:37-47.

Early kidney cancer produces no symptoms and is most likely to be discovered incidentally by ultrasound or computed tomography (CT) imaging carried out for some other reason. More advanced tumours can cause haematuria, back pain, and an abdominal mass. Renal cell cancers may also cause fever.

Treatment is primarily surgical. These cancers tend not to respond to chemotherapy although immunotherapy is sometimes effective. Metastatic spread may involve lymph nodes, bones, liver, lungs, brain and other organs.

Prevention

The evidence on risk factors for this group of cancers suggests that there is substantial scope for prevention. Population-wide initiatives aimed at reducing smoking and improving diet are highlighted as government priorities. These could lead to substantial reductions in the number of people who develop urological cancers.

Half the cases of urinary tract (bladder or kidney) cancer in men and a third of cases in women are likely to be due to smoking.[31] Effective interventions for reducing smoking are described in the document on lung cancer in this series (*Improving Outcomes in Lung Cancer: The Manual)*. It is unlikely, however, that prostate cancer rates would be affected significantly by action against smoking.[42] Dietary improvements – specifically, increased consumption of vegetables and fish, and decreased consumption of dairy produce and meat – might reduce the prevalence of symptomatic prostate cancer.[19,43] Increased fruit and vegetable consumption is also likely to reduce the risk of other urological cancers.[19,44] Finally, interventions to reduce obesity and hypertension could reduce the prevalence of kidney cancer.[40]

There is no reliable evidence showing that population screening reduces mortality rates from any form of urological cancer. Systematic reviews have concluded that screening for prostate cancer using PSA testing cannot be justified on the basis of current evidence.[4,7]

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[42] Lumey LH. Prostate cancer and smoking - a review of case-control and cohort studies. *Prostate* 1996;**29**:249-60.

[43] Working Group on Diet and Cancer, Committee on Medical Aspects of Food and Nutrition Policy. *Nutritional aspects of the development of cancer*. London: Department of Health, 1998.

[44] La Vecchia C, Negri E. Nutrition and bladder cancer. *Cancer Causes Control* 1996;**7**:95-100.

Current services in the NHS

One of the problems that has been highlighted in urological cancer services is the delay between referral and diagnosis. Long delays are relatively common, particularly for patients with cancers of the prostate, bladder, renal pelvis and ureter. 33% of patients referred by GPs to urologists have to wait for more than 12 weeks between referral and diagnosis; 12% wait more than 24 weeks. Table 8 shows the length of delay for 15,543 patients after referral to urologists.[35] These figures suggest that there are major problems with urological diagnostic services.

Table 8. Time between referral to urologist and diagnosis (excluding patients diagnosed before referral)

Organ	Mean (days)	Median (days)
Prostate	115	60
Bladder	83	54
Kidney	67	38
Testis	27	13
Kidney pelvis/ ureter	117	64
Penis	52	33

Structure and quality of current services

Patients with the more common urological cancers are managed by urologists working in local district general hospitals, sometimes in collaboration with oncologists. Co-ordinated multidisciplinary team structures are not common in urology.

There is little information on the quality of current services but there is evidence that delays in diagnosis and treatment are greater for patients with prostate and bladder cancers than for those with other common cancers. Both time to first out-patient appointment and time to first definitive treatment are, in general, substantially longer for prostate and bladder cancer than for breast, colorectal, lung, gynaecological, or upper gastro-intestinal cancers. A study of waiting times for all patients newly diagnosed with cancer in 1997 found that men with prostate cancer endured the longest delays - 53 days (median) to first definitive treatment for cases referred as urgent, 111 days for non-urgent cases.[45]

[45] Spurgeon P, Barwell F, Kerr D. Waiting times for cancer patients in England after general practitioners' referrals: retrospective national survey. *BMJ* 2000;**320**:838-9.

The fragmentation of services for patients with urological cancers is reflected in the low numbers of radical operations for prostate and bladder cancers performed each year in most NHS Trusts (Table 9). (See also, the evidence section of Topic 1, *The urological cancer network and multidisciplinary teams.*)

Table 9. Radical surgery for prostate and bladder cancer in NHS hospitals: activity by region, 1999-2000

Region	Population (millions)	Number of radical prostate-ctomies + cystectomies	Number of Trusts	Number of Trusts doing 50+	Number of Trusts doing <6
Northern & Yorkshire	6.4	322	17	2	4
Trent	5.1	195	14	0	3
West Midlands	5.3	243	21	0	9
North West	6.6	271	24	0	8
Eastern	5.4	284	17	0	1
London	7.2	384	25	0	6
South East	8.6	392	24	1	4
South West	4.9	267	17	0	5
English Subtotals	**49.5**	**2358**	**159**	**3**	**40**
Wales	2.9	135	10	0	4
Overall Totals	**52.4**	**2493**	**169**	**3**	**44**

Source: Hospital episode statistics (HES) data for England; Patient episode data for Wales (PEDW).

Provisional NHS service configuration

Most patients with urological cancer will be treated locally, in district general hospitals which have both urology services and cancer units. These hospitals will form part of wider networks designed to provide co-ordinated services at many levels. Local hospitals will need to collaborate to generate the workload necessary to support increased specialisation among urologists, a minority of whom will develop expertise in the management of urological cancers.

Each network will include the following key parts:

- GPs/primary care teams. The management of patients with prostate cancer, in particular, requires considerable primary care involvement since many of the men affected live with slowly advancing cancer for years.

- Dedicated clinics in local district general hospitals which have both urology services and cancer units; these will be responsible for rapid diagnosis and initial assessment.

- Treatment and palliative care services at local hospitals, where patients will be managed by multidisciplinary teams.

- Support and information services for patients and carers. These will be linked with social services, particularly services for the elderly.

- Specialised palliative care services and facilities such as hospices, which may be provided in partnership with the voluntary sector.

- Specialist multidisciplinary teams, most of which will be based in cancer centres, providing more technically challenging forms of treatment for selected patients. Most networks will have one such team; larger networks may have two.

- Specialist services at supra-network level which will manage patients with testicular, penile, and complicated kidney cancers.

Representatives from the whole network will work with members of specialist urological cancer teams to develop treatment and referral protocols and ensure that the service works in a co-ordinated way. Non-surgical oncologists will work across networks, providing services at the local level.

The urological cancer network and multidisciplinary teams

A. Recommendations

The network

Each cancer network provides and co-ordinates a wide range of services for patients with urological cancers within a defined geographical area. Different degrees of specialisation are required to deal with the various types of cancer, and multidisciplinary teams (MDTs) should be established in cancer units, cancer centres, and at supra-network level; these will be distinct teams, although there is likely to be overlap between their members. All teams should participate fully in the urological cancer network, and all members of teams should be involved in discussions on local policy decisions and in auditing adherence to them.

All patients with urological cancer – both new and existing – should be managed by appropriate MDTs. Documented clinical policies for referral and treatment should be agreed between cancer leads in primary care and lead clinicians representing urological, oncology and palliative care services throughout the network, and signed off by the lead clinician for the network. Effective systems will be required to ensure rapid communication and efficient co-ordination between teams.

Local urological cancer teams should be established in cancer units at district general hospitals. Specialist urological cancer teams should be based in larger hospitals, usually cancer centres. There are various possible ways of providing local services which meet the criteria defined in this Manual; local teams may be set up by individual Trusts; two or more Trusts may work in partnership; and some services could be provided by mobile teams. Although there should not be more than one MDT of any specific type working in a single hospital, a centre serving a large population may have teams at different levels of specialisation.

Substantial changes in working practice will be required to create the form of service described here. Each network should decide how it will establish the specialist teams which are central to these recommendations. Some clinicians working in cancer units may wish

to join a specialist urological cancer team based in another hospital; where this pattern of practice is adopted, all such individuals should participate fully in team meetings. All teams should include sufficient members to allow for adequate cover for the absence of any individuals and all members should meet the attendance criterion (attending more than half of the meetings of the team in which they work).

It is recognised that a period of transition will be required before the new pattern of service provision is established. In the meantime, all surgeons who carry out fewer than five radical prostatectomies or fewer than five cystectomies per year should pass this work to more specialised colleagues.

The local urological cancer team

In general, local urological cancer teams should serve populations of 250,000 to 500,000, but the minimum figure may be closer to 200,000 in large sparsely populated areas. Core teams should include, at a minimum, the members specified below. All members of each team should have a particular interest in urological cancer and treatment should be provided by these designated individuals.

Those who are directly involved in treating patients (in particular, urologists, oncologists and cancer care nurses) should recognise that they have responsibility for good communication with patients and carers, and should receive specific training in communication skills.

Members of the local urological cancer team

- Designated lead clinician (normally a consultant urologist) who will take overall responsibility for the service.

- Urologists. The team should include a minimum of two designated urologists with a special interest in cancer.

- Designated nurse who will provide information and support for patients. This nurse may, if suitably trained, carry out a range of interventions such as digital rectal examination, flexible cystoscopy, and intravesical treatment for patients with resected superficial bladder cancer.

- Radiologist with expertise in urological cancers. All imaging investigations should be carried out in accordance with Royal College of Radiologists Guidelines.[46]

[46] The following guidelines are available from the Royal College of Radiologists: Johnson R, Husband JE (Eds) *Guidelines for the use of CT scanning in the investigation of common malignancies* (1995); Husband JE, Johnson RJ, Reznek RH. *A guide to the practical use of MRI in oncology* (1999); RCR Working Party. *Making the best use of a Department of Clinical Radiology: Guidelines for Doctors (Fourth Edition)*. London: The Royal College of Radiologists, 1998. A fifth edition of this booklet is due to be published in 2002.

- Pathologist. Pathology reports should include all the information required by the current Royal College of Pathologists' minimum dataset for the relevant cancer.[47] A national histopathology quality assurance (EQA) scheme should be established along the lines of the EQA scheme for breast cancer, to be run by those directly involved in this work.

- Oncologist with expertise in radiotherapy and chemotherapy for patients with urological cancers. The oncologist, who is likely to be a member of the specialist urological cancer team from a linked cancer centre, should co-operate with other specialist oncologists in the network.

- Palliative care specialist (physician or nurse).

- Team co-ordinator (see below, *Organisation of MDT meetings,* for discussion of this role).

- Team secretary who will provide clerical support for the MDT. The secretary should record all decisions made by the team and communicate appropriate information promptly to all those (such as GPs) who may require it. The roles of secretary and co-ordinator overlap and one person may be able to cover both functions in smaller teams.

The role of the local urological cancer team

This team will:

- Provide a rapid diagnostic and assessment service;

- Identify and manage all patients with urological cancers, including those cared for elsewhere in the hospital;

- Be responsible for the provision of information, advice and support for all patients and their carers throughout the course of the illness; this should include those who are receiving most of their care from clinicians who are not members of the urological cancer team, such as physicians for care of the elderly;

- Provide treatment and follow-up for these patients and ensure that every patient with urological cancer receives multidisciplinary management with appropriate oncological input;

- Provide a rapid referral service for patients who require specialist management;

[47] The Royal College of Pathologists' minimum datasets for specific cancers are available on http://www.rcpath.org/activities/publications.

- Liaise with primary care teams, specialist teams, services for the elderly and voluntary organisations such as hospices;
- Ensure that GPs are given prompt and full information about any changes in their patients' illness or treatment;
- Collect data for network-wide audit.

The team must maintain close contact with all other professionals who are actively involved in treating or supporting patients. These will include the following:

- Stoma nurse;
- Liaison psychiatrist;
- Clinical psychologist trained in psychotherapy and cognitive behaviour therapy;
- Trained counsellor with expertise in cancer and psychosexual problems;
- Social worker;
- Occupational therapist;
- GPs/primary health care teams;
- Palliative care teams;
- Clinical geneticist/genetics counsellor.

Arrangements should be made to alert an appropriate member of the core team whenever a patient managed by that team is admitted to hospital for any reason, both so that the team may contribute to decision-making about diagnosis or treatment and to ensure that it has up-to-date information about such patients.

The team should meet weekly and should assume responsibility for all patients with urological cancers. All team members should attend the majority of meetings and all should participate in collaborative decision-making.

Decisions about management and standards for therapy should follow documented clinical policy which has been agreed throughout the network. This policy should be demonstrably evidence-based and should be produced jointly by members of all the teams in the network which deal with patients with urological cancer.

One member of the team (usually the lead clinician) should take managerial responsibility for the service as a whole. Audit of processes and outcomes, and action stimulated by audit findings, should be discussed in team meetings. Data collection systems should be compatible with those used at the cancer centre to facilitate network-wide audit.

Specialist urological cancer teams

Patients with cancers which are less common or require complex treatment should be managed by specialist multidisciplinary urological cancer teams. These teams should be established in large hospitals or cancer centres, and each team should carry out a cumulative total of at least 50 radical operations for prostate or bladder cancer per year. All operations carried out by any particular team should be carried out in a single hospital, which should also provide post-operative care and host the MDT meetings.

In larger cancer networks (those providing services for urological malignancies for populations of two million or more), a second specialist team may be established, provided the population served by each of the teams is no less than one million. Any non-centre teams should be capable of the full range of activities required of specialist teams and must be able to demonstrate strong clinical links to the radiotherapy centre and associated non-surgical oncology services at the cancer centre.

Where two specialist teams are established within one network, there should be strong links between them. They should jointly establish common clinical policies across the network as a whole, and for the audit of all aspects of their work. Each team should appoint a lead clinician who will take an active role in the co-ordination of urological cancer services provided by the network as a whole.

Specialist urological cancer teams should manage the following types of patient. The figures given in brackets for each category of patients are the numbers likely to require complex or radical surgery each year in a population of one million.

- Men with early-stage prostate cancer for whom surgery is considered appropriate and who elect to undergo radical prostatectomy (25-50).

- Patients with muscle-invasive bladder cancer (50). Patients with high-risk superficial tumours should be formally discussed with the specialist team; some of these will require referral for management by the specialist team. There should be specific local protocols which define these patients and give details of appropriate referral and management.

- Patients with kidney cancer who fall into the following categories (20-30):
    - Those with tumours which have, or may have, invaded major blood vessels;
    - Patients who might benefit from resection of metastases;
    - Patients with bilateral disease or who will require dialysis;
    - Patients with small tumours for whom nephron-sparing surgery may be possible;
    - Patients with von Hippel-Lindau disease or hereditary papillary tumours.

Supra-network specialist teams

Patients with testicular or penile cancer should be managed by specialist testicular cancer or penile cancer teams working at the supra-network level. Such teams should serve up to four networks, with a combined population base of at least two million for testicular cancer and four million for penile cancer. (See Topic 6, *Testicular cancer*, and Topic 7, *Penile cancer.*) These teams should liase closely with local urological cancer teams which will be responsible for some aspects of the diagnosis and treatment of these cancers.

Members of specialist urological cancer teams

The MDT described below should be regarded as a generic form; additional members are required for teams treating male genital cancers at the supra-network level, as specified in Topic 6, *Testicular cancer* and Topic 7, *Penile cancer*. Each member of a specialist urological cancer team should have a specialist interest in urological cancer and all team members must attend a majority of meetings. The team should carry out a cumulative total of at least 50 radical operations for prostate or bladder cancer per year.

The specialist urological cancer team should include one or more of each of the following individuals:

- Urologists. There should be at least two urologists in the team.
- Clinical oncologist.
- Medical oncologist, except where the clinical oncologist has specific expertise in systemic treatment for urological cancers.
- Radiologist with expertise in urological cancers. All imaging investigations should be carried out in accordance with Royal College of Radiologists Guidelines. [46]

- Pathologist. Pathology reports should include all the information required by the current Royal College of Pathologists' minimum dataset for the relevant cancer.[47] The pathologist should participate in a national histopathology quality assurance (EQA) scheme.

- Clinical nurse specialist. This role is similar to that of a breast care nurse. The nurse must have a high level of skill in communication because patient advocacy and provision of information and support for patients and carers are crucial aspects of the role. (See Topic 3, *Patient-centred care*.)

- Pain management and palliative care specialist(s). Some palliative care specialists may be nurses but consultant input and advice will be necessary.

- Team co-ordinator, who will organise meetings and ensure that all documentation (such as patient lists and case notes) that may be required to inform discussion is available at each meeting.

- Team secretary, who should provide clerical support for the MDT, record decisions, and communicate information generated by the MDT to all those who may require it.

The team should have access to critical care facilities. It should maintain close contact with other professionals who may be actively involved in supporting patients or carrying out the management strategy decided by the team, so that rapid access to their services can be provided when required. These include the following:

- GPs/primary health care teams;

- Local urological cancer teams at linked cancer units;

- Plastic surgeon;

- Thoracic surgeon;

- Liaison psychiatrist;

- Clinical psychologist trained in psychotherapy and cognitive behaviour therapy;

- Counsellor with expertise in treating psychosexual problems;

- Stoma care nurse;

- Lymphoedema specialist;

- Occupational therapist;

- Social worker;
- Palliative care teams.

Organisation of MDT meetings (local and specialist teams)

Meetings should be arranged by the team co-ordinator, who should ensure that information necessary for effective team functioning is available at each meeting. This will include a list of patients to be discussed and copies of their case notes, along with diagnostic, staging, and pathology information.

Preparation and attendance at meetings should be recognised as clinical commitments and time should be allocated accordingly. Team members should be adequately prepared for each meeting, so that they can discuss each case without delay.

All new patients should be discussed, along with any other patients whose cases are thought to require discussion as their condition or treatment progresses. Straightforward cases may need very little discussion but they should nevertheless be included.

Audit, clinical trials, and other issues of relevance to the network should also be discussed at MDT meetings.

Suitable facilities should be provided to support effective and efficient team working. In addition to the basic physical facilities such as adequate room and table space, these are likely to include, for example, appropriate equipment to allow the whole group to review large numbers of radiographic images and pathology slides. Teams may consider taking formal training to facilitate effective group working.

Co-ordination between teams

Close co-ordination is required between primary care teams, diagnostic and treatment teams at cancer units and cancer centres, palliative care teams, and patients and their families. There should be a designated individual in each team who has responsibility for communication and information provision, and adequate support must be provided to ensure that all decisions about patient management are recorded. (See the role of team secretary/co-ordinator, above.)

Clearly defined arrangements should be made to ensure that appropriate information (including the name of the clinician and nurse specialist who are directly responsible for each patient) is communicated promptly to patients and others (such as GPs) who may require, or may benefit from, information about decisions concerning particular patients. GPs should be given sufficient information about each patient's cancer and management for them to advise and support patients and their carers.

Trusts should produce patient-held information packs. These should contain details of the patient's disease and treatment, relevant MDT(s), clinical appointments, and a diary in which patients can record symptoms and other potentially useful information about their condition, both for the patients' own use and to help clinicians who may see them out of hours to respond appropriately to their needs.

B. Anticipated benefits

Re-structuring services for urological cancers to increase specialisation and establish multidisciplinary team working is expected to produce wide-ranging benefits for patients and the NHS.

A co-ordinated cancer network should be capable of delivering consistent, efficient and effective care to all patients in the region it covers. Within each level of the service, team working will facilitate co-ordinated care. Patients managed by teams which function effectively are more likely to be offered appropriate information and guidance, to receive continuity of care through all stages of their disease, and to be treated in accordance with locally-agreed protocols and clinical guidelines.

Increasing specialisation will tend to refine surgical expertise, provide the necessary conditions for training in uro-oncology for specialist registrars and newly appointed consultants, and permit meaningful audit of individual outcomes. This will enhance the level of skill available within the NHS.

Discussion of every patient by multidisciplinary teams will improve patient-centred care by ensuring that psychosocial, as well as clinical, issues are considered; these issues tend to be raised by nurse specialists and others who bring different perspectives from those of urologists and oncologists. It provides an opportunity for pathology and radiology results to be discussed and allows the team as a whole to check that everything necessary is done for the patient.

It is anticipated that these changes, implemented together, will lead to significant improvements in outcomes for patients with urological cancers.

C. Evidence

Note: The reliability and quality of evidence supporting the recommendations is graded A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Multidisciplinary teamwork

There is little direct research evidence for the effectiveness of multidisciplinary teamwork in the management of patients with urological cancer. Nevertheless, there are a number of strands of evidence which, considered together, point to the value of this model of working.

In prostate cancer, in particular, patients are faced with difficult decisions about treatment options. As the evidence summarised in Topic 5, *Prostate cancer* shows, there is often no convincing evidence for the overall superiority of any particular approach to treatment over others. Uncertain benefits of treatment have to be balanced against potentially deleterious effects on quality of life. In this situation, specialists have a natural tendency to prefer, and to recommend, active treatment using the modality in which they specialise. Most tend to under-value conservative options such as active monitoring.

These biases have been documented in studies of the attitudes and behaviour of urologists and oncologists treating men with prostate cancer.(B) They have also been reported by patients, who find the experience of hearing conflicting recommendations from different specialists distressing.(C)

Insights from the Cancer Services Collaborative

Two case studies of action to improve the effectiveness of MDT meetings discussing patients with prostate cancer have been reported by the Cancer Services Collaborative in England.(C) The initial problems – poor attendance by team members and failure to discuss all the patients who should have been discussed – were common to both and were solved by similar strategies.

These strategies had two main elements. The first was improved team-building, with involvement of all team members in discussions about meetings. The second was the introduction of effective systems to ensure that all new patients were discussed and that necessary information (such as case notes and results of diagnostic investigations) was available for each patient at the meeting. Documentation was improved using, in one case, a *pro forma* developed specifically for these meetings, and in the other, an information sheet designed to aid communication.

Both case studies reported improvements in attendance rates and the effectiveness of meetings. The proportion of patients discussed by the teams also rose. One study reported a dramatic increase in the percentage of patients managed in accordance with clinical guidelines, from 10% before the introduction of the MDT *pro forma* and action to ensure the availability of patients' notes, to 100% eight months later.

Further information can be obtained from the Cancer Services Collaborative Service Improvement Guide on Multidisciplinary teamworking at www.nhs.uk/npat.

Specialist management

It is rarely possible to separate the effects on outcomes of specialist management and high patient throughput; in practice, the former is not achievable without the latter – although it is conceivable that, in some hospitals, large numbers of patients may be treated by relatively unspecialised clinicians.

There is consistent evidence showing the benefits of either higher patient throughput or higher levels of institutional specialisation in both prostate and testicular cancer. Systematic reviews and individual studies which examine relationships between the number of patients treated and the quality of treatment received show that care in high volume institutions is associated with significantly better outcomes.(B)

For radical surgery for prostate cancer, the cut-off points for high and low volumes vary between studies, but all show a progressive improvement in outcomes from the smallest centres (25 or fewer prostatectomies per year) to the largest (over 140 per year). Hospitals which manage larger numbers of these patients report lower complication and mortality rates and lower resource use.

In one review of outcomes after radical prostatectomy, in-hospital mortality rates were almost identical in low and medium volume hospitals (<25 or 25-54 prostatectomies per year), and significantly poorer than in higher volume hospitals (>54 prostatectomies per year); odds ratios 1.8 and 1.7 for low and medium volumes (95% CI: 1.2 to 2.7 and 1.2 to 2.6, respectively), compared with higher volumes. Serious complications and re-admissions showed the same pattern: the highest patient numbers were associated with the lowest risk. Compared with hospitals which carried out more than 140 prostatectomies per year, the risk of serious complications was 43% greater (95% CI: 37% to 48%) in hospitals which carried out 39 or fewer prostatectomies, 25% greater (19% to 31%) for a volume range of 39-74, and 9% greater (3% to 15%) when volumes were between 75 and 140. However, simply increasing the throughput of patients managed by established institutions may not be sufficient to improve outcomes.(B)

In testicular cancer, too, there is a clear relationship between patient numbers treated and the quality of care provided. Patients treated in institutions which deal with larger numbers of such cases are significantly more likely to survive.(B) (See also Research Evidence for Topic 6, *Testicular cancer*.)

Further evidence supporting concentration of services comes from a review focusing on specialisation, which reported reduced mortality rates among patients treated for urological cancers by specialists, or in hospitals linked with universities.(B)

Studies of pathology services in prostate and testicular cancer have found that specialised centres produce more accurate reports on

biopsy specimens. Histopathological review by experts can result in crucial changes in management; for example, a study of testicular tumour pathology found that expert review led to a major change in diagnosis in 6% of cases.(B)

Current services in the NHS

NHS services for the more common forms of urological cancer are fragmented, with most hospitals treating small numbers of these patients. Hospital episode statistics (HES) show that about two-thirds of the hospitals which carry out prostatectomy, and over three-quarters of those which carry out cystectomy, do 10 or fewer of each operation per year. Table 10 and Figure 2, below, show frequency distributions of Trust workload for radical surgery for prostate and bladder cancer in England between 1995 and 2000.

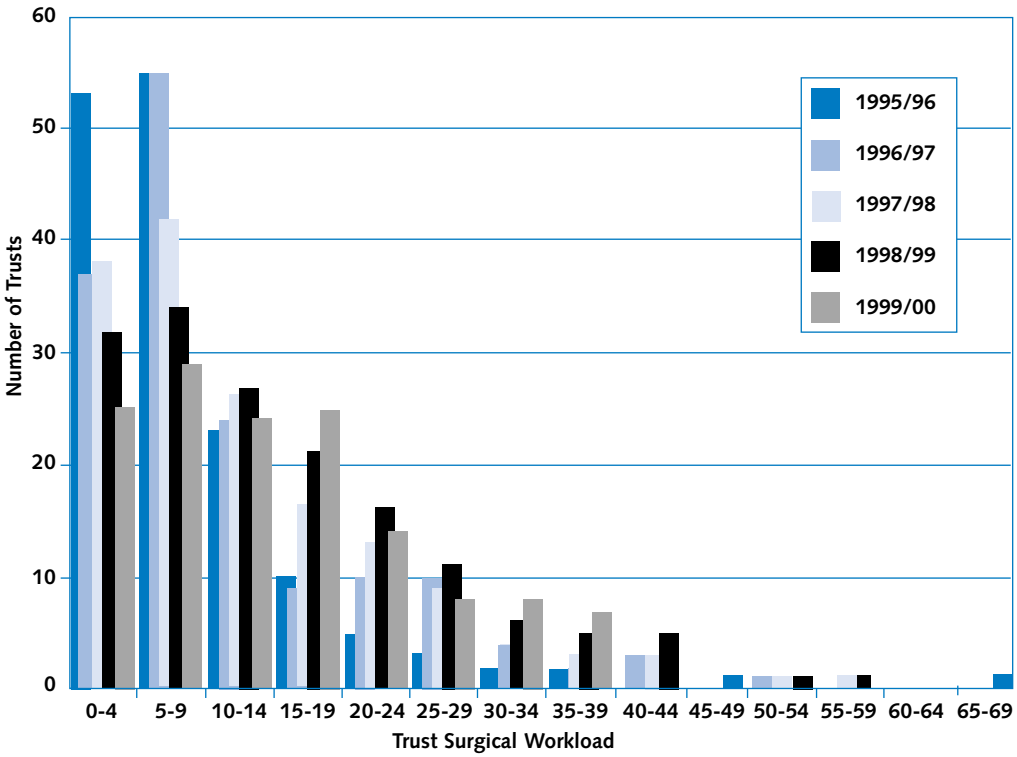
Table 10. Frequency distribution of Trust workload for prostatectomy and cystectomy combined (England)

Number of operations per Trust*	1995/96	1996/97	1997/98	1998/99	1999/00
0-4	53	37	38	32	25
5-9	55	55	42	34	29
10-14	23	24	26	27	24
15-19	10	9	16	21	25
20-24	5	10	13	16	14
25-29	3	10	9	11	8
30-34	2	4	4	6	8
35-39	2	2	3	5	7
40-44		3		3	5
45-49					1
50-54	1		1		1
55-59			1	1	
60-64					
65-69					1
Grand Total	**154**	**154**	**153**	**156**	**148**

* "Operations" refers to the combined total of radical prostatectomies and cystectomies carried out for cancer treatment by individual Trusts in a specified year.

Whilst it is clear that workload patterns are changing in the direction of higher volumes and, presumably, greater specialisation, there is a long way to go before the criteria recommended in this Manual can be met. Just two hospitals in England provided 50 or more radical operations (prostatectomies plus cystectomies) for prostate or bladder cancer in 1999-2000, 7.4% of the total number done (2,358 operations).

Figure 2. Frequency distribution of Trust workload for prostatectomy and cystectomy combined (England)



Although HES data provides a fair picture of the general situation in the NHS, HES figures are not precisely correct. The accuracy of HES data depends on the quality of coding, both for disease and procedure, and errors occur when patients with cancer are not identified or the nature of surgery is incorrectly described. In addition, recent Trust mergers mean that data for more than one treating hospital may be included in a single figure, overstating hospital workload. Despite these limitations in the data, there is no reason to doubt the overall picture of low rates of radical urological surgery in individual NHS hospitals.

D. Measurement

Accreditation standards for multidisciplinary teams to deal with urological cancers will be published in the NHS *Manual of Cancer Service Standards* in England and in the Minimum Standards for Cancer Services in Wales.

Structure

- A network in which the roles of hospitals which offer services for patients with urological cancer are specified.
- Systems to link and co-ordinate the activities of hospitals within the network.
- Appropriate teams in place in each hospital in the network.
- Adequate systems and support for rapid communication between teams within the network.
- Evidence-based assessment, treatment and referral guidelines, agreed by specialist teams throughout the network.
- Systems for network-wide audit of procedures and outcomes.
- Provision of adequate and appropriate facilities for surgery and post-operative care.

Process

- Evidence of weekly MDT meetings at both cancer units and centres.
- Records showing that every individual member of each MDT is present at a majority of meetings.
- Evidence that every patient with cancer has been discussed in an MDT meeting.
- Comparison of total number of patients diagnosed in each Trust with number reviewed by relevant MDTs.
- Use of locally agreed clinical policies and guidelines.
- Number of patients managed annually by each team.
- Number of cystectomies and radical prostatectomies carried out by each team; the sum total of these operations should come to more than 50 per year.
- Audit of time taken to communicate essential information about individual patients (e.g. diagnosis and treatment plan) between hospital staff and primary care teams.
- Number of patients choosing each form of treatment.

Outcome

- One, two and five-year survival rates for each type of cancer, adjusted for case-mix.

- Audit of outcomes of treatment, including detailed information on case-mix.

E. Resource implications

At the time of writing, there are few genuine MDTs in urological cancer. Implementing these recommendations will require far-reaching changes in working practices and establishment of new staff posts within the team. For example, a larger number of clinical nurse specialists and team co-ordinators will be required than are currently in post, and time has to be set aside by all those involved to attend team meetings. Increased resources will be required over a considerable period for re-structuring of urological services, for training, and to achieve sufficient numbers of professionals to work in these teams.

- The additional annual costs of ensuring that all MDTs have a co-ordinator, an additional consultant session, and additional staff time for MDT meetings are estimated at £6.4 million (see Appendix 1, *Economic implications of the guidance*).

- The cost consequences of the centralisation of radical surgery for bladder and prostate cancers to teams in specialist centres is between £3.8 and £5.0 million (see Appendix 1, *Economic implications of the guidance*).

Diagnosis and assessment

The following guidelines for urgent referral (within two weeks) have been published by the Department of Health:[48] Similar guidelines for patients at high risk of urological cancer have been published in Wales.[49]

- Macroscopic haematuria in adults.
- Microscopic haematuria in adults over 50 years.
- Swellings in the body of the testis.
- Palpable renal masses.
- Solid renal masses found on imaging.
- Elevated age-specific prostate specific antigen (PSA) in men with a 10 year life expectancy.
- A high PSA (>20ng/ml) in men with a clinically malignant prostate or bone pain.
- Any suspected penile cancer.

A. Recommendations

Diagnostic investigations in primary care

GPs within each network should work with members of specialist urological cancer teams to develop and circulate locally agreed guidelines on appropriate referral for patients with suspected urological cancer. Compliance with these guidelines should be audited.

[48] Department of Health. *Referral Guidelines for Suspected Cancer.* Available on http://www.doh.gov.uk/cancer.

[49] National Assembly for Wales. *Urological Cancer Services All Wales Minimum Standards.* Available on http://www.wales.gov.uk/subihealth/content/cscg/index.htm

Prostate cancer
GPs should use digital rectal examination (DRE) to assess lower urinary tract symptoms (such as frequency, hesitation, poor stream) suggesting obstructive disease of the prostate or bladder neck. If the prostate feels normal, the option of PSA testing may be discussed with patients but appropriate counselling, including information about the reliability of PSA results and acknowledgement of uncertainty about the balance of risks and benefits, should be given before a PSA test is carried out. Patients should be offered material designed to promote informed choice about PSA tests, available through the National electronic Library for Prostate Cancer.[14] Any patient with a prostate that feels abnormal, or whose symptoms or test results suggest the possibility of prostate cancer, should be referred to a prostate assessment clinic (see below).

Testicular cancer
Only a small proportion of men with scrotal swellings have cancer; a GP may see only one case of testicular cancer every 20 years and is not likely, therefore, to be able to distinguish between tumours and non-malignant causes of symptoms. GPs should refer men with testicular masses or other unexplained testicular symptoms such as a sensation of scrotal heaviness or pain, to a testicular assessment clinic (see below).

Penile cancer
GPs should refer men with suspicious penile lesions such as growths, swelling at or near the glans, painless ulcers which do not appear to be due to infection, or other unexplained abnormalities such as plaques on the skin or foreskin of the penis, to a local urological cancer team.

Bladder and kidney cancer
Most patients with bladder or kidney cancer develop visible haematuria and they should be referred within two weeks to a dedicated haematuria clinic. Patients with kidney cancer may also present with persistent loin pain; such patients should be referred for imaging.

Patients (particularly those over 50 years of age) with persistent irritative urinary symptoms which do not respond to antibiotic treatment should be referred for further investigation.

Diagnostic services in district general hospitals

Prostate assessment clinics and haematuria clinics should be provided by urology departments of district general hospitals. These clinics should be staffed by diagnostic teams with members drawn from the local urological cancer multidisciplinary team (MDT), and should include a nurse with special responsibility for providing information and support for patients. Urologists and other clinic staff should give patients clear reasons for investigations and explain the implications of results. (See Topic 3, *Patient-centred care*.)

Diagnostic services should be organised, where possible, so that they can carry out sufficient tests to determine whether cancer is present during a single visit. The concept of a one-stop clinic should not be taken to imply that all diagnostic tests should be offered in a single location or necessarily carried out at the first visit. Ultrasonography, for example, may be carried out in a radiology department but the MDT should aim to synchronise imaging with other diagnostic investigations so that delays are minimised.[50]

When successive appointments are necessary, they should be pre-booked to minimise delay between investigations. An appointment to discuss results should be arranged for a date within two weeks of the initial investigation appointment. Patients should be encouraged to bring a close friend or relative to any meeting at which they are expected to receive news of a diagnosis of cancer.

Prostate assessment clinics should provide DRE and PSA testing, as well as trans-rectal ultrasound (TRUS) and needle biopsy, carried out by a suitably trained health professional.

Haematuria clinics should offer clinical examination, urine testing, flexible cystoscopy, and rapid access to ultrasound imaging and intravenous urography (IVU) when required. When an abnormality or growth in the bladder is apparent but the diagnosis is uncertain, patients should be told that a definite diagnosis cannot be given until pathology results are available.

Arrangements also need to be made for rapid assessment of scrotal swellings using ultrasound; this service may be provided as part of general urology or elsewhere, as judged appropriate locally. All diagnostic and assessment services should follow documented clinical policies which have been agreed throughout the network.

Staff who carry out diagnostic investigations such as biopsy should have received adequate and appropriate training in the techniques they use, to minimise the potentially high error rate. When prostate biopsy proves negative but there is strong suspicion that cancer is present (for example when the PSA level remains persistently high), re-biopsy is necessary. Local clinical protocols should include specific criteria to guide judgements in such cases.

[50] An appropriate model might be the one-stop clinic for diagnosis of breast cancer. Mammography is often carried out in a different part of the hospital from the breast clinic, but diagnostic investigations are integrated so that patients do not have to wait for long periods.

Diagnostic investigations in secondary and tertiary centres

Prostate cancer

TRUS and prostate biopsy may be carried out by a suitably trained health professional working in a prostate assessment clinic. Pathology reports should include all the information required by the current Royal College of Pathologists' minimum dataset for prostate cancer.[51] When biopsy samples suggest the presence of cancer and radical treatment is being considered, pathology results should be reviewed by the pathologist member of the specialist urological cancer team at the centre at which such treatment would be carried out. A national histopathology quality assurance (EQA) scheme should be established along the lines of the EQA scheme for breast cancer, to be run by those directly involved in this work.

Magnetic resonance imaging (MRI) may have a role in the pre-operative assessment of patients who are considered to be at intermediate or high risk (PSA above 10ng/ml, Gleason score 5 or more), who might benefit from radical treatment and whose cancer does not appear to have spread beyond the prostate. All images held by local MDTs should be forwarded to the appropriate specialist MDT if radical surgery is being considered.

Networks should agree and document clinical policies for the use of bone scans in urological cancers. Routine bone scanning is not necessary for all patients with prostate cancer. In particular, it is not likely to be useful for previously untreated men with PSA levels below 10ng/ml and Gleason scores below 8, who are free from bone pain. Such men are very unlikely to have metastatic disease.

Testicular cancer

Testicular cancer can be reliably confirmed or excluded by a combination of clinical examination and ultrasound imaging. Men with scrotal swellings should be assessed in regular clinics equipped with ultrasound facilities capable of producing precise images and staff who are skilled in interpreting ultrasound images of the scrotum.

If ultrasound and clinical examination suggest the presence of cancer, blood should be taken before surgery to assess levels of tumour markers including alpha-fetoprotein (AFP), lactate dehydrogenase (LDH) and beta-human chorionic gonadotrophin (βhCG). The results of these assays should be available within one week. Laboratory techniques for measuring these tumour markers should be agreed by the whole network, to ensure consistency across the network.

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[51] The Royal College of Pathologists. *Minimum dataset for prostate cancer histopathology reports*. Available on http://www.rcpath.org/activities/publications/prostate.html.

Most patients should undergo orchidectomy before referral to a specialist testicular cancer MDT at a designated cancer centre, except when there are clear signs or symptoms of metastatic germ cell cancer. These patients should be referred immediately to the specialist MDT.

The risk of cancer in the contralateral testis and the option of biopsy should be discussed with patients. Biopsy and surgical samples should be reviewed by a histopathologist member of the testicular cancer MDT.

Bladder and other urothelial cancers

The majority of patients will be assessed in haematuria clinics, described earlier in this section. Assessment of bladder cancer normally requires diagnostic resection. If initial assessment suggests that the patient has a low-grade superficial tumour, resection can be carried out by a urologist member of the local urological cancer MDT who has an interest in bladder cancer. This resection should be sufficiently deep to determine the depth of tumour invasion. Pathology reports should include all the information required by the current Royal College of Pathologists' minimum dataset for bladder cancer.[52]

About 50% of patients will have high-risk superficial tumours or muscle-invasive cancer (T2 or above). Patients with G2 or G3 tumours should be formally discussed with the specialist urological cancer team. Those who have pT2 or more advanced tumours should be referred to the specialist team; images produced at local hospital or unit level should be sent with the patient for review by the specialist team. MRI, or computed tomography (CT) if MRI is not available, should be used to assess the extent of invasive tumours before radical treatment. Patients with high-risk tumours should have the opportunity to discuss the implications of the results of staging investigations in a joint meeting with a surgeon and an oncologist.

Tumours of the upper urological tract are relatively unusual. These tumours are linked with bladder cancer and the same grading system is used. Assessment and staging requires urinary cytology, ureteroscopic biopsy, and CT imaging.

Kidney cancer

The diagnosis of kidney cancer is usually made by imaging. All patients with renal masses which could be malignant should be referred to the local urological cancer team.

[52] The Royal College of Pathologists. *Minimum dataset for bladder cancer histopathology reports*. Available on http://www.rcpath.org/activities/publications/bladder.html.

CT is required to assess local invasion and spread to lymph nodes. The lungs should be scanned using CT to check for metastatic disease, except in patients with small tumours (up to 3cm), for whom chest x-ray may be sufficient. If it appears that tumour may have invaded the renal vein or inferior vena cava, or if nephron-sparing surgery might be possible, patients should be referred to the specialist urological cancer team, which should arrange further assessment including MRI. Biopsy is not normally necessary before surgery; it should be reserved for selected cases when imaging is unclear or surgery is not appropriate and biological treatment is being considered.

B. Anticipated benefits

The establishment of dedicated clinics for the assessment of haematuria and prostate-related symptoms is expected to reduce delays in diagnosis of the more common forms of urological cancer. Currently, many patients with urological cancers experience long delays before a definitive diagnosis is achieved and treatment begins. It is unclear whether such delays affect survival rates, but they can cause considerable distress to patients.

The Cancer Services Collaborative in England has demonstrated that a prostate assessment clinic with a pre-booked appointments system can reduce delays from as much as six months to less than one month. When diagnostic services are not only efficient, but sensitive and responsive to patients' needs, this tends to establish a pattern of harmonious relationships between patients, carers and service providers.

Accurate staging and pathology results are essential to inform decision-making about therapy.

C. Evidence

Note: The reliability and quality of evidence supporting the recommendations is graded A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Prostate cancer

Detection and initial diagnosis

Prostate cancer may produce no symptoms until it has reached an advanced stage, but early cancer can be detected by DRE, which is used to investigate lower urinary tract symptoms. In older men, these symptoms are often caused by benign prostatic hyperplasia, with which cancer may co-exist.

DRE is quick and minimally invasive and when negative, usually means the patient does not have prostate cancer (negative predictive value 0.99, 95% CI: 0.98 to 0.99). The positive predictive value of DRE is low in the context of primary care (0.28, 95% CI: 0.20 to 0.36), so a positive result cannot be used to make a diagnosis but does indicate a need for further investigation and/or referral.(B)

The most-studied diagnostic test for prostate cancer is the PSA assay. PSA rises with the burden of disease and is generally highest – often over 100ng/ml – in men with metastatic disease. Prospective screening studies have found that a quarter to a third of men with PSA over 10ng/ml have prostate cancer but PSA levels vary widely, both among men who do have cancer and those who do not. There is no criterion below which men may be reassured that they do not have cancer, nor an agreed level which is regarded as diagnostic. Different systems for measuring PSA can produce quite variable results and apparent changes in PSA levels can reflect the use of assay materials from different manufacturers. In addition, sexual activity, clinical investigation and some forms of treatment can affect PSA levels.(B)

TRUS is used to estimate prostate size, guide needle biopsy and stage tumours. Biopsy is necessary for histological confirmation of cancer, but this too can produce very variable results, depending on operator skill and the method used. Re-biopsy can be positive for cancer in a substantial proportion of cases when initial biopsy was negative but other investigations suggest the presence of cancer. Adverse effects of prostate biopsy include pain, bleeding and infection; they have been reported to occur in up to 13.5% of patients who receive antibiotic cover and up to 34% of those who do not.(B)

Assessment of stage and local spread

Information on the stage and spread of prostate cancer can be obtained from PSA, DRE, TRUS, CT and MRI, and accurate assessment requires an appropriate combination of these. Clinical assessment of early prostate cancer tends to underestimate the stage of the tumour, often failing to detect when tumour has spread beyond the capsule of the prostate. In a recent study, 13% (17 of 131) of men who were believed on the basis of clinical assessment (including DRE) to have organ-confined disease, actually had bone metastases.

Accurate imaging is essential to assess the extent of apparently localised prostate cancer if radical treatment is being considered, because surgery is not likely to be curative when the tumour has spread beyond the capsule. Ultrasound, although invaluable for guiding biopsy, is not adequate for informing decisions of this sort except in low-risk patients.

Two studies suggest that that MRI is more useful than CT for assessing extracapsular extension and invasion of seminal vesicles and lymph nodes.(B) However, these were poor quality studies and imaging technology has improved since they were carried out. MRI is however, recommended as the staging method of choice for prostate cancer by the Royal College of Radiologists.[53](C)

Metastatic disease

In the UK, about 20% of men have metastatic disease, usually affecting the bones, when their prostate cancer is first diagnosed. PSA level is the best biochemical marker for bone metastases, which are very rare in untreated men with PSA below 10ng/ml.(B) Only a minority of men with PSA levels between 10 and 50ng/ml have metastatic disease, and efforts have been made to find a criterion which offers the optimum compromise between sensitivity and specificity. Levels of 35 and 70ng/ml have been proposed on the basis of receiver operator characteristic (ROC) curves.(B)

Bone pain in men with prostate cancer is usually due to metastatic disease. In one study, all patients with bone pain and PSA levels over 20ng/ml had metastatic disease.(B) A US review of 288 patients who were classified as "at risk" of bone metastases if they had abnormal acid phosphatase, alkaline phosphatase or bone pain found that only 1.4% of men who had none of these had metastases (B). Poor overall functioning is also associated with metastatic disease.(B)

Bone scans are generally used as the "gold standard" to detect bone metastases but it is not clear from the research evidence that these, on their own, are actually more accurate than the combination of symptoms and appropriate blood tests. Bone scans are appropriate, however, for assessing men with bone pain, since they can be used to inform management.

Testicular cancer

Initial diagnosis

No review of research evidence was carried out to assess the effectiveness of ultrasound for the initial diagnosis of testicular cancer. There is consensus in the clinical community that this is the most appropriate form of investigation.(C)

Assessment of metastatic disease

CT is generally more accurate than plain film chest radiography (x-ray) for detection of lung metastases. The use of both chest radiography and CT is not justified.(B)

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[53] Husband JE, Johnson RJ, Reznek RH. *A guide to the practical use of MRI in oncology.* London: The Royal College of Radiologists, 1999.

Bladder and kidney cancers

Detection and initial diagnosis

Most patients with cancers of the bladder or kidney present with visible haematuria. This may be intermittent but a single episode of haematuria can signal the presence of cancer. Clinic-based studies suggest that 15% to 37% of patients with visible haematuria may have cancer, with higher proportions in areas where substantial numbers of people work in hazardous industries (see *Background*).(B)

Microscopic haematuria is common in young men and is rarely associated with any pathology, but it is a better predictor of cancer in older men. A large study (n=1,930) based in a Newcastle hospital haematuria clinic found that 9.4% of patients with microscopic haematuria had cancer. Although the probability of cancer increased with age, it was found in a few men below the age of 40.(B)

Bladder and kidney cancers are unusual in people less than 40 years old. The incidence of both rises steeply with each decade between the ages of 40 and 60, rising from 9.2 per 100,000 in men aged 40-44 to 36.5 per 100,000 in men aged 50-54, and 109.5 in those aged 60-64. The incidence in women shows a similar rate of increase with age, but the proportion affected in each age-group is less than half the corresponding proportion of men.(B)

Assessment of tumour stage and spread

The Royal College of Radiologists states that "MRI is superior to CT for staging bladder cancer" and recommends that MRI should be the staging method of choice.[54] (C) Published comparative studies do not show a consistent advantage for MRI over CT but these studies are all rather old and the technology has improved.(B) In renal cell cancer, CT is adequate for assessing most tumours but MRI may be marginally more accurate for staging.(B)

Quality of current services

A study of the management of muscle-invasive bladder cancer in the South West Region in 1989 and 1993 revealed clear evidence of deficiencies. The median delay between GP referral and diagnostic cystoscopy was 59 days in 1989 and 52 days in 1993; there were then further delays of 55 days (1989) and 44 days (1993) between cystoscopy and treatment. This brings the total period for median delay to more than three months in both 1989 and 1993. Inadequacies were reported in diagnosis and staging, with poor recording of details of pathology and stage of tumours. Similar problems were found in all types of hospital.(B)

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[54] Husband JE, Johnson RJ, Reznek RH. *A guide to the practical use of MRI in oncology*. London: The Royal College of Radiologists, 1999, p 46.

More recent data shows that waiting times may be long in England as a whole. Median time before the first out-patient appointment for NHS patients newly diagnosed with bladder cancer in 1997 was 20 days for urgent cases, 33 days for those classified as non-urgent; time to first definitive treatment was 57 and 82 days for these groups, respectively. 10% of urgent patients had to wait four months or more before their treatment began.(B)

The situation is even worse for patients with prostate cancer. An audit of delays experienced by patients with localised prostate cancer in south west England in 1993 found that some men waited for more than a year after their first clinic appointment before treatment began. This study also reported serious deficiencies in assessment, staging, documentation, and communication between the various clinicians involved in patient care.(B) The study described in the previous paragraph found that for England as a whole, waiting times were longer for men with prostate cancer than for patients with any other common cancer.(B)

The Cancer Services Collaborative in England has reported on pilot studies of a variety of initiatives designed to reduce delays in diagnostic services for prostate cancer.(C) These studies provide information both on the situation that existed before the initiative was launched (November 1999), and on ways of streamlining services to improve the experience for patients.

The Collaborative found that the established pattern in the NHS was for diagnostic investigations to be undertaken in sequence, with each successive investigation arranged only when the results from the previous one became available. This creates built-in delays. The introduction of rapid-access and one-stop clinics, along with pre-booking systems for diagnostic appointments, led to impressive reductions in delay. Examples of successful initiatives in diagnostic services include the following:

- In Leicester General Hospital, waiting time from referral to diagnosis was cut from 36 weeks to 3-4 weeks by the establishment of a prostate assessment clinic.

- One-stop clinics in three Trusts in the Bristol area now allow patients to have counselling, examination and appropriate investigations on a single day, with a follow-up appointment for results 10 days later.

- In Liverpool, a wait of 6-18 weeks for a staging bone scan was reduced to two weeks for appropriate patients by the introduction of protocols.

- In Colchester, patients had to wait for up to three months before getting their prostate biopsy results. The delay was reduced to a maximum of two weeks by re-organising the appointments system.

- Patients in West London waited eight weeks for TRUS and biopsy, and a further two weeks to hear the results. Now, biopsy is done either the same day as the first consultant appointment or within a week, and it is pre-scheduled. The total delay has been reduced from 10 weeks to two or less.

Further information is given in the Prostate Cancer Service Improvement Guide, available from the Cancer Services Collaborative (www.nhs.uk/npat).

D. Measurement

Structure

- Establishment of rapid-access and one-stop clinics for assessment of patients with possible urological cancers.

- Efficient appointment systems designed to minimise delay between referral and diagnosis.

Process

- Completion of current form of Royal College of Pathologists' histopathology dataset for each patient, where appropriate. This represents a minimum standard for pathology.[55]

- Time between date of receipt of GP referral letter and first hospital appointment.

- Time between first clinic appointment and diagnosis.

Outcome

- Patients' satisfaction with services.

- Stage distribution at time of diagnosis.

[55] The Royal College of Pathologists. *Standards and minimum datasets for reporting cancers*. Currently published for adult renal, bladder, prostate and testicular tumours. Available on: http//www.rcpath.org/activities/publications/minimum datasets.

E. Resource implications

The direct resource implications specific to the recommendations in this topic are modest.

- They include £0.28 million for bladder cancer and between £0.23 million and £0.4 million for pre-operative MRI imaging for prostate cancer. These are offset by savings of £0.34 million to £0.58 million for bone scans (see Appendix 1, *Economic implications of the guidance*).

- However, the rising incidence of prostate cancer coupled with greater use of PSA testing will increase both diagnostic and treatment costs (see Topic 5, *Prostate cancer*).

Patient-centred care

A. Recommendations

The recommendations in this section call for major changes in the provision of care for patients with urological cancers. Nurse specialists will play a crucial part, both in ensuring that patients receive adequate support and information, and in shaping the way that urological cancer multidisciplinary teams (MDTs) work. These aspects of the nurse specialist's role, although relatively new to urology, are particularly well developed in services for patients with breast cancer.

Communication with patients

In urological cancer in general, and prostate cancer in particular, the appropriate management strategy for an individual patient may depend crucially on that individual's values and attitudes. Because of the nature of the disease and the unpredictable rate of progression, the optimum strategy is often unclear. Radical treatment carries the threat of incontinence and permanent damage to sexual function and enjoyment, which may be unacceptable to some patients – especially when there is uncertainty about the degree of survival benefit that such treatment may offer. Others may feel that such risks are of little significance compared with the prospect of living with cancer.

In this situation, shared decision-making is essential. This can only work if patients are sufficiently well informed to understand the choices they face, and have sufficient time to consider the options carefully.

Patients should be given as much information as they wish to have, in language they are likely to understand, and in both verbal and written forms. When English is not the patient's first language, somebody who speaks the patient's language should be available to facilitate communication. Providers should not expect members of the patient's family to act as interpreters.

Patients should be given written material in information packs (see Topic 1, *The urological cancer network and multidisciplinary teams*) to which additional material can be added as required. Each pack should contain up-to-date information about the patient's disease and treatment, the names of MDT members responsible for his or her care, and clear information about services, including the following:

- A description of the way the clinics and doctors function together, and their various responsibilities.

- The way the appointments system operates.
- Contact details for people with whom patients or carers can talk if they feel concerned about any aspect of the illness, its treatment, or the hospital service.
- A telephone number for the nurse specialist member of the MDT responsible for his or her care.

Information offered to patients should also include:

- Sufficient information about basic anatomy and pathology for patients and their carers to understand how the disease might affect them.
- Realistic information about the disease and the range of individual variation in its impact and rate of progression.
- Information about known causes of the patient's type of cancer, including occupational risk factors if relevant.
- The aims, risks and likely effects of proposed diagnostic procedures. Each procedure should be explained to the patient before it is undertaken.
- Balanced information about potential treatment options, including the probability of improved survival or symptom reduction (and uncertainties about benefits), known risks and potential short- and long-term adverse effects.
- The likelihood of long-term continuing contact with the urological cancer team.
- Reasons for not offering interventions which patients might anticipate.
- Information on action that patients can take to help themselves and sources of support for such action – e.g. quitting smoking, improving their diet.

Patients should receive individual support and guidance from members of the MDT, as well as well-produced information leaflets. When patients have a choice between different therapeutic modalities, they should be offered the opportunity to discuss treatment options in a joint meeting with their urologist, oncologist, and specialist nurse.

Providers should ask patients if they want additional information and seek to discover how much they wish to be involved in discussions about treatment. Patients should be encouraged to bring a close friend or relative to the "bad news" consultation.

Clinicians must be sensitive to potential problems with communication, and those who provide direct patient care – particularly senior clinical staff - should have training in communication skills. They need to be aware that patients often find it difficult to take in information given during the consultation, especially just after receiving bad news.

Sensitive communication of bad news is particularly important to patients. The "bad news" consultation should be carried out in a private room without interruptions. The diagnosis should be explained clearly by a senior clinician who must allow adequate time for explanation and a specialist nurse should be present. After the consultation, the specialist nurse should offer to remain with the patient to provide support and further information tailored to individual needs. The Mount Vernon guidelines on handling the communication of bad news[56] should be followed.

All health professionals involved with each patient should know what information has been given to the patient. A record of this, along with the patient's preferences for information and involvement in decision-making, should be included in the notes and given to the patient's GP, together with a comprehensive summary of the management plan, as quickly as possible, so that primary care staff can provide additional support for patients and carers.

Advice for smokers

Patients with bladder or kidney cancer should be asked if they smoke and smokers should be strongly advised to quit. The association between smoking and urological cancer should be explained, and the benefits of quitting explicitly linked with reduced risk of recurrence. Smokers should be given information about local initiatives designed to help them quit and encouraged to participate.

Psychological support, sexual issues, continence and fertility

From the time of diagnosis, each patient should have access to a specialist cancer nurse who can offer psychosocial support and continuity of care. Patients should, whenever possible, be offered contact details for others who have experienced similar cancers or treatments; this may be arranged through Patient Advocacy and Liaison Services (PALS). Appropriate patients should be given information about organisations which offer specific forms of support such as The Association to Aid the Sexual and Personal Relationships of People with a Disability (SPOD)[57].

The nurse specialist, or another member of each MDT, should be trained in counselling patients and couples who may have to live with impotence or other sexual problems, loss of fertility, incontinence or

[56] The Mount Vernon guidelines and a Patient Information Card can be obtained from the King's Fund by ringing 020 7307 2672. The King's Fund has also published a book, *Breaking Bad News* (ISBN 1-85717-135-7).

[57] Telephone number: 020 7607 8851; www.spod-uk.org.

stomas after treatment for cancer. Psychological and psychosexual issues should be discussed with every patient who may experience adverse effects in these areas before final decisions are made about treatment. Counselling should be available when required from an individual who has specific expertise in dealing with psychosexual and body-image issues; this should be available to help patients and their partners to cope with such problems after treatment and for as long as it is needed.

Patients who may have problems with urinary incontinence should be given information both about local continence services and the Continence Foundation.[58]

Arrangements for cryopreservation of sperm should be explained to men whose ability to father children could be reduced by treatment. This is likely to be particularly relevant to men with testicular cancer.

Practical and social support

Many patients, particularly those with prostate cancer, are over 70 years of age. They, and their carers, are likely to require long-term support. The primary and palliative care teams have particularly important roles in co-ordinating with social services and ensuring that the needs of both patients and carers are identified and met.

Patients should be given information about sources of help, such as local and national support groups and disability and benefits helplines, both verbally and in writing. Information about support groups of various kinds is provided by NHS Direct and by cancer charities.[59]

B. Anticipated benefits

Provision of clear and timely information can help patients to cope with their disease, enhance satisfaction with services, and reduce criticism and complaints. Sensitive delivery of bad news is particularly valued by patients.

Information has a variety of benefits for cancer patients, particularly anxiety reduction, improved ability to cope with treatment and better self-care. Effective communication tends to heighten awareness of the various needs - whether medical, practical or psychological - of patients and carers, and increase the probability that these needs can be met.

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[58] Information about the Continence Foundation can be found on www.continence-foundation.org.uk. The Foundation provides a helpline on 020 7831 9831.

[59] Websites which provide information on support groups for cancer patients and carers can be obtained from NHS Direct (Tel: 0845 4647)

C. Evidence

Note: The reliability and quality of evidence supporting the recommendations is graded A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Communication and information

Insights from patients treated for urological cancer

Patient focus groups, convened to discuss services for urological cancers, emphasised the importance for decision-making of good information on adverse effects of treatment and long-term quality of life. The communication of bad news was specifically highlighted; the nature of this experience seems to influence patients' views about subsequent interactions with health services. In particular, patients value the following:

- Privacy and lack of interruption during the "bad news" interview;
- Diagnosis given by a senior clinician;
- Clarity; patients prefer clinicians to use the word "cancer", thus avoiding confusion when they explain the diagnosis;
- Appropriate timing and adequate time for explanation;
- Sensitive mode of communication;
- Immediate support and information after the interview, tailored to individual needs and provided by a specialist nurse.

Patients reported problems with inadequate information during and after treatment. Lack of information left them bewildered, fearful, and unable to cope with long-term adverse effects of treatment such as incontinence. Some reported conflicting information from different clinicians and a specific lack of information about brachytherapy, about which they learnt from the internet. They wanted more support in decision-making about treatment options and more information about known adverse effects of treatment.

Whilst patients did not expect clinicians to be able to predict the future – especially in metastatic disease – they did want to know what might happen to them, and what support services were available. In particular, they wanted advice and support to help prepare for whatever the future might hold. Contact with other patients who had undergone similar experiences was valued.

Research evidence

The review of research evidence did not identify any studies which specifically addressed communication and information needs of patients with urological cancers. The following conclusions have been drawn from studies which included patients with a variety of cancers.

Problems with communication between clinical staff and patients can cause unintended distress. Although some patients may not wish to take an active part in decision-making, there is consistent evidence that they value accurate information and that many feel they are not given sufficient information. Studies demonstrating both patients' desire for information and its beneficial effects are summarised in the Research Evidence for previous documents in this series, in particular *Improving Outcomes in Lung Cancer.*

The following strategies have been found to be effective for improving communication:

- Doctors asking patients directly, in a structured way, whether they would like to know about particular issues.(A)

- Providing patients with a questionnaire (using the word "illness", not "cancer"), to elicit their concerns.(A)

- A taped or written record of the consultation. Although a majority of patients find audiotapes helpful, they can increase distress in those whose prognosis is poor and some patients do not wish to receive them. It is important that staff check that the patient does want a record of the consultation before it is given.(A)

- Patient-held shared-care records or information folders which hold details of appointments, medication, strategies for symptom control, contact addresses and telephone numbers, and a diary of significant events.(B)

- Provision of specific, easily-understood information about the nature and effects of any treatment before it begins, and on the management of pain and other symptoms at home. Such information can reduce anxiety and lead to more effective symptom control and self-care.(A)

- Cancer information booklets, videos, tapes and telephone help-lines. Whether these provide specific information, for example on pain management or anti-cancer treatments, or more general information on cancer, they are appreciated by patients and carers alike.(A)

Training in communication skills can change the attitudes of health professionals, improve their methods of eliciting and offering information, and increase their confidence in their ability to deal with patients with cancer.(B) The benefits appear to be greatest for people who hold particularly negative attitudes before training.(B) Some studies suggest that improvements can be maintained for several years, but training which fails to address participants' concerns may not be effective, as the skills learnt will not be put into practice.(B)

Psychosocial interventions

Cancer has profound effects on the lives of patients and their families, touching them at every level. They may need psychotherapeutic help or social support at any point, from initial diagnosis to death and bereavement. Estimates of the prevalence of psychiatric morbidity in patients with advanced cancer range from 37% to 63%.(B)

The research evidence is consistent in showing that social support and psychotherapeutic or psycho-educational interventions can improve patients' quality of life. A wide range of psychological interventions can reduce anxiety, depression, nausea, vomiting and pain;(A) cognitive therapy designed specifically for patients with cancer is significantly more effective than supportive counselling.(A) Home support by an oncology nurse during periods of out-patient treatment may reduce anxiety and depression.(A)

One small study (n=73) of patients with newly diagnosed testicular cancer found that routine cognitive/behavioural treatment was ineffective for this group.(A) Such interventions may be more appropriate for patients who are experiencing difficulty in coping with their situation.

D. Measurement

Structure

- Evidence that patients are given appropriate and adequate verbal and written information about their cancer, proposed treatments and options, and sources of practical help.
- Training courses in communication skills for clinical and other staff.
- Clinical nurse specialists who have had training in counselling patients with cancer.
- Facilities and support for patients' mutual support groups.

Process

- Private rooms used for crucial meetings between health care staff and patients (in particular, consultations at which patients are given bad news).
- There should be evidence that patients receive information and support from the time of diagnosis from suitably trained staff.
- There should be evidence that every patient has access to a named nurse specialist who knows about his or her condition and who can offer advice and arrange meetings with appropriate health or social services staff when required.
- The proportion of staff involved in direct patient care who have had specific training in communication and counselling skills should be monitored.

Outcome

- Providers should carry out surveys of patients' experience to assess the adequacy of each component of patient-centred care, including patient knowledge about available resources and patients' views on the quantity of information and the manner in which it was given.

E. Resource implications

- Additional resources may be necessary for the provision of information and educational material for patients with urological cancers.
- Resources will be required to allow sufficient staff time for provision of help and support for patients.
- Adequate training in communication skills and psychosexual counselling for nurses and other clinical staff is likely to require additional resources.
- Expansion in the numbers of specialist nurses is recommended. These staff have a range of roles including patient support and improving communications. The overall cost of expanding numbers of specialist nurses is £2.68 million (see Appendix 1, *Economic implications of the guidance*).

Palliative care

Supportive and palliative care guidance is currently being developed under the auspices of the National Institute for Clinical Excellence (NICE). This section deals with the structure of palliative care services. Interventions for palliation of symptoms associated with advanced urological cancer are discussed in the context of specific cancers, in particular prostate cancer.

A. Recommendations

Palliative care should be an integral part of patient management. Specialist palliative care teams should be available to arrange the provision both of relief from symptoms and social and psychological support for patients and their carers when these needs cannot be met by primary care teams.

Patients with advanced urological cancer may require care from specialist cancer treatment teams, specialist palliative care teams and primary care teams. Palliative care teams should work closely with primary care teams and hospital services; rapid and effective communication and information-sharing between teams is essential.

Specific services should be established for patients with advanced urological cancers. The majority of these will be men with prostate cancer, who may live with slowly progressing disease for a decade or even more, but there will also be men and women with other forms of advanced urological cancer. All need care that evolves to fit their changing requirements. These services should be linked with other primary and palliative care services.

Criteria for referral for specialist care should be agreed and documented for the whole network by palliative care specialists and representatives from primary care and specialist treatment teams. Primary care teams should assess patients' needs regularly and accurately, to ensure that patients who require specialist palliative care or interventions (see below) are referred quickly and appropriately.

The specialist palliative care team

Palliative care is essentially a local service, and specialist palliative care teams should be based both in hospitals that manage patients with urological cancer, and in the community. The role of the specialist palliative care team includes both direct care for patients and families with complex problems, and the provision of advice, support and education for other health professionals. One member of the team should be responsible for ensuring co-ordination of palliative care services and rapid communication, both between professionals and with patients and their families.

The specialist palliative care team should be multidisciplinary, and should, as a minimum, include the following members:

- Palliative care physician.
- Palliative care nurse specialists.

The team should have close links with the following:

- Physiotherapist.
- Clinical psychologist.
- Liaison psychiatrist.
- Social worker.
- Occupational therapist.
- Chaplain/pastoral care worker who can offer counselling and spiritual guidance for patients with advanced incurable illness and their carers.
- Bereavement care worker.
- The primary care team.

Patients, their carers, GPs and hospital staff who care for these patients should have access to a member of the specialist palliative care team at any time of the day or night. A named member of the team should be responsible for ensuring effective co-ordination of palliative care services, continuity of care, and rapid communication, both between professionals and with patients and their families.

The team should endeavour to make it possible for patients to spend their remaining life in the place they prefer, whether this is home, hospital or hospice, but should be alert to the possibility that this preference may change as death approaches.

Management of patients with advanced disease

All patients with advanced cancer should be asked regularly if they have pain, so that prompt action may be taken to relieve it. Cancer pain can normally be controlled with oral or parenteral analgesics, usually opiates, in accordance with the World Health Organisation (WHO) 3-step method for control of cancer pain.[60] This requires regular and frequent assessment of pain, with titration of the dose of analgesia against pain severity.

There should be a system for rapid referral for radiotherapy for palliation of pain, particularly when it is associated with bone metastases. Urgent access to radiotherapy, orthopaedic and neurosurgical services should be available for patients at risk of fractures or spinal cord compression. (See Topic 5, *Prostate cancer*.)

B. Anticipated benefits

Prompt identification and appropriate action to manage problems experienced by patients is crucial to reduce their distress and disability and diminish strain on carers. High quality co-ordinated palliative care services can improve quality of life for people with advanced cancer, and effective home care can usually keep symptoms sufficiently well controlled to allow patients to stay at home for as long as they wish. This is preferred by most patients and may be the least expensive option for the NHS.

C. Evidence

Note: The reliability and quality of evidence supporting the recommendations is graded A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Patients' needs

Advanced urological cancer and its treatment can cause pain, fatigue, mobility problems, fractures, constipation, urinary retention or incontinence, impotence, psychological distress and problems with social relationships. Palliative care and support must be multi-faceted and responsive to the needs of individual patients; conventional care alone is not sufficient.

Patients with advanced disease can receive high quality care in a variety of settings, including hospitals, hospices, and their own homes, so long as there is adequate input from specialists who can offer pain and symptom control when required. Older primary

[60] World Health Organisation. *Cancer Pain Relief*. Geneva: World Health Organisation, 1996.

studies showed poorer management of pain for patients in their homes than in the institutional environment, but this appears to have improved in recent years.(B)

Palliative home care teams have small but positive effects on outcomes for both patients and carers. Pain, symptom control and levels of satisfaction can be improved by specialist home care team involvement.(B)

A systematic review of studies which compared "standard home care" with interventions based in hospitals, hospices or the community, suggests that standard care alone may not be sufficient. Additional interventions may be required for patients who remain at home, to control physical symptoms and reduce the need for re-admission. Favourable results were reported in studies of palliative home care teams when members held regular meetings and visited patients at home.(B)

Current NHS services

The Department of Health undertook a national stocktake of palliative care services across England in 1999. The results of this survey, mapped in collaboration with the Office of National Statistics, is available on the Department of Health cancer website (www.doh.gov.uk/cancer). For all categories of provision – day care, home care, hospice and specialist palliative in-patient care, and hospital support – a majority of health authorities in every region reported shortages. Only 14 of 99 health authorities were able to report adequate provision of all types of service.

D. Measurement

Structure

- Documented local clinical policies to guide referral for palliative care.
- Evidence that appropriate palliative care services are available in hospitals, hospices and the community, and that their resource and staff levels are adequate.
- Appropriate facilities for rehabilitation and palliative care.
- Specialist palliative care teams which meet specifications given in the NHS *Manual of Cancer Service Standards* in England, and the Minimum Standards for Specialist Palliative Care as applied to Cancer Services in Wales.
- Systems to permit 24-hour access to specialist advice on palliative care.

- Arrangements to facilitate prompt access to specialist interventions, including specialist pain control.
- Availability of rapid access to radiotherapy and orthopaedic services.
- Evidence of effective communication systems for information-sharing between all levels of the service and all those involved in individual patient management.

Process

- Audit of home visits made by palliative care team members.
- Evidence of regular meetings of palliative care teams.
- Audit of time to provision of specialist palliative interventions.
- Audit of speed of provision and appropriateness of equipment supplied by occupational therapists to patients in the community.

Outcome

- Audit of symptom control.
- Proportion of patients who suffer bone fractures or spinal cord compression.

E. Resource implications

Improved co-ordination of care could reduce costs per patient, but improving access to specialist palliative care services is likely to require increased resources in many areas. These changes are not specific to patients with any particular type of cancer.

Prostate cancer

Profound changes are anticipated in services for prostate cancer and it is recognised that, for many Trusts, establishing the structures described in this Manual will be a gradual process. Full implementation of the recommendations below may only be possible when other components of the service, in particular the multidisciplinary team (MDT) structure, have been set up. These recommendations, therefore, describe services towards which networks should work.

A. Recommendations

Early (organ-confined) prostate cancer

The prostate cancer service should be capable of providing active monitoring, radical surgery, radiotherapy, or hormone treatment for men whose cancer is believed to be confined to the prostate. All possible management options should be discussed with patients.

There is no consensus on the optimum form of management for these patients. Although observational studies suggest that radical treatment can improve long term survival rates in particular patient groups, this evidence is by its nature subject to bias. In addition, the uncertain benefits of radical interventions must be balanced against the risk of lasting adverse effects. Research – both randomised controlled trials and audit of outcomes outside the context of clinical trials – is essential to clarify the role of each form of treatment and should be supported.

Different men vary greatly in the value they ascribe to potential outcomes. The treatment each patient receives should be tailored to fit his individual values and situation, so it is essential that patients are actively involved in decision-making. This requires that they receive adequate and accurate information, both through meetings with members of the MDT, and in published forms that they can study at home. Patients should be given sufficient time to consider all the options available to them. (See Topic 3, *Patient-centred care*.)

Active monitoring

Active monitoring aims to detect disease progression as early as possible. This allows intervention to be avoided when the patient's condition is stable, whilst permitting prompt action to control symptoms and reduce the risk of serious problems when the cancer is progressing.

The option of active monitoring should be discussed with all men whose tumours are believed to be confined to the prostate. This form of management is particularly suitable for those who, because of advanced age or poor general health, have a life expectation of less than 10 years. Monitoring should involve regular clinical review and assessment of the prostate using prostate specific antigen (PSA) and digital rectal examination (DRE). When symptoms or rising PSA levels suggest that the cancer is progressing, the case should be reviewed by the MDT and treatment options again discussed with the patient. Patients who are considering active monitoring should be encouraged to participate in EORTC trial 30991, which is randomly allocating men with early prostate cancer to hormone therapy or "watchful waiting".

This strategy requires well co-ordinated shared care involving urological services, palliative care, and primary care teams. Patients should be managed in accordance with protocols which should be agreed by all relevant MDTs in the network and disseminated to all those who are likely to be responsible for their care.

Hormone therapy

The possibility of hormone treatment – orchidectomy (surgical castration) or treatment with an anti-androgen or Luteinising hormone-releasing hormone (LHRH) agonist – should be discussed with these patients.

Surgery

Radical prostatectomy should be discussed with men whose tumours are confined to the prostate and who would be expected to live for more than 10 years if they did not have prostate cancer.

Patients for whom surgery is being considered should be treated by specialist multidisciplinary urological cancer teams, normally based at cancer centres. (See Topic 1, *The urological cancer network and multidisciplinary teams.*) Ideally, all radical prostatectomies undertaken in each network should be carried out by a single team. Radical prostatectomy should not be carried out by teams which carry out fewer than 50 radical operations (prostatectomies and cystectomies) for prostate or bladder cancers per year.

This level of work-load is currently unusual in the UK and a transition period is likely to be required for re-organisation of services before the criterion of 50 operations can be met. In the meantime, surgeons who currently carry out fewer than five radical prostatectomies per year should refer patients to designated surgeons who will become more specialised in this type of surgery.

Laparoscopic prostatectomy is not recommended outside the context of well-designed clinical trials supervised by experienced surgeons. Proficiency in this procedure requires considerable practice and inexperienced surgeons can cause serious harm.

Radiotherapy

The option of radiotherapy (external beam or brachytherapy) should also be discussed with men with early disease. Conformal radiotherapy, using multileaf collimators which allow treatment using an irregularly shaped beam, is the optimum mode of delivery and all centres should aim to provide this form of treatment. Radiotherapy should be given by specialist clinical oncologists from, or in, the centre. Outcomes, including adverse effects, should be carefully monitored.

As with other forms of radical treatment for prostate cancer, the place of brachytherapy is uncertain. However, it offers the advantages of speed and convenience and there is demand from some patients for this form of treatment. Centres which offer brachytherapy should evaluate their outcomes with particular care. A large scale, nationally or internationally co-ordinated, research project is necessary to assess the effectiveness of brachytherapy for localised prostate cancer. A randomised intergroup trial comparing brachytherapy with radical surgery is being organised by the National Cancer Institute of Canada and the American College of Surgeons Oncology Group (NCIC CTG Study PR.10/ACOSOG Z0070). This will evaluate the advantages (equivalent disease control with reduced morbidity) in patients with localised disease (T1c or T2a N0 M0), claimed by enthusiasts for brachytherapy. UK participation in this study should be strongly encouraged through the appropriate National Cancer Research Institute (NCRI) Clinical Studies Groups and clinical research networks.

Continuing care

There should be documented clinical policies for shared care for men with prostate cancer managed in the community. These policies should specify criteria for referral back to the local urological cancer team. Telephone follow-up by the specialist nurse in the urological cancer team who is familiar with the patient's case should be offered to appropriate patients.

Primary care teams, patients and carers should have access to the specialist nurse, who should provide telephone advice and arrange rapid referral to the treatment team when required.

Locally advanced disease

Hormone therapy, with or without external beam radiotherapy, should be discussed with men whose tumours extend beyond the confines of the prostate. Suitable patients should be encouraged to enter the MRC PRO7 trial of hormone treatment with or without radiotherapy.

Metastatic disease

Hormone therapy

Men with advanced or metastatic prostate cancer should be offered orchidectomy (surgical castration) or treatment with an anti-androgen or LHRH agonist. All these options should be discussed with patients, who should be encouraged to make a choice based on their personal values and the likely balance of benefits and adverse effects. Hormone treatment should not be deferred if there is a risk of spinal cord compression. Maximum androgen blockade is not normally recommended.

Patients with metastatic disease in remission should remain under careful observation so that treatment can be provided promptly when further symptoms develop.

Treatment for bone metastases

For some patients with prostate cancer, bone pain is the first symptom. Short courses of radiotherapy should be available for patients with bone metastases. Treatment with radioisotopes should be considered for men with bone pain at multiple sites. There is growing evidence that bisphosphonates may be beneficial for men with prostate cancer but no definite recommendations can yet be made.

Severe backache should be regarded as a warning of possible spinal cord compression. Patients should be informed about this risk and about the importance of contacting the MDT if they experience new or worsening backache. There should be systems to permit rapid access to diagnosis and treatment for patients who could be at risk of fracture or spinal cord compression.

Other palliative interventions

Chemotherapy should be considered for men with symptomatic hormone-refractory prostate cancer and trials of this form of therapy should be supported. Palliative radiotherapy should also be available.

B. Anticipated benefits

Appropriate management of prostate cancer should maximise patients' quality of life and may improve their life expectancy. Well-designed research studies and better routine monitoring of outcomes will help to provide the information necessary to judge which forms of treatment are most suitable for individual patients.

Concentration of services for patients with early tumours in the hands of highly-skilled specialists is likely to increase the probability of appropriate treatment and decrease the frequency and severity of

adverse effects. Wider use of conformal radiotherapy will permit better disease control with lower levels of adverse effects among men who undergo radiotherapy.

Improved access to treatment for metastatic prostate cancer is likely to reduce both patients' suffering and the burden on the health service of catastrophic fractures and spinal cord compression.

C. Evidence

Note: The reliability and quality of evidence supporting the recommendations is graded A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Early prostate cancer

Radical interventions compared with active monitoring

Radical treatment – prostatectomy or radiotherapy – can control local symptoms of prostate cancer but can also cause significant complications, particularly impotence, proctitis and incontinence. There is no reliable evidence showing whether or not it improves survival. Large-scale prospective randomised trials are essential to resolve uncertainty about the relative effectiveness of different forms of treatment.

A new trial, ProtecT, has been set up by the Health Technology Assessment programme to compare outcomes in men with screen-detected prostate cancer treated with radiotherapy, radical prostatectomy or active monitoring. This is expected to produce important data and should be supported. As its starting point, the ProtecT trial assumes absolute equipoise between active monitoring, radical prostatectomy and radical radiotherapy, for all patients irrespective of age or tumour grade.

Other RCTs comparing active monitoring with radical treatment are in progress outside the UK, but these will not produce useful data on survival rates for some years.

Many non-randomised studies suggest that prostate cancer-specific survival rates are higher among men who undergo radical prostatectomy, but a variety of sources of bias – all of which tend to exaggerate the possible survival benefit associated with surgery – have been identified. First, there is selection bias: the fittest men tend to be selected for surgery. Second, studies have generally been analysed according to treatment received rather than intention to treat; consequently, the benefits of radical prostatectomy have been over-estimated. Finally, there is evidence of bias in reporting cause of death, such that deaths among patients who have undergone radical treatment for prostate cancer are significantly more likely to be

ascribed to other forms of cancer than would be expected in this population.(B) This would create the illusion of improved prostate cancer-specific survival rates even if radical treatment had no effect at all.

A US population-based study using information on almost 60,000 men in the Surveillance, Epidemiology, and End Results (SEER) database has assessed the effects of different management strategies on survival. Although this is weak evidence, it is the best currently available. Outcomes were sub-divided by tumour grade, which is the most important predictor of progression in prostate cancer. Overall, the risk of dying from prostate cancer was 10 times higher among men with high-grade tumours (Gleason score 8-10) than those with low-grade tumours (Gleason score 2-4).(B) This pattern is consistent with results reported in other studies.

The effectiveness of radical treatment varied with tumour grade. There was no difference in the 10-year prostate cancer-specific survivals for men with low-grade tumours, whether they elected to undergo radical prostatectomy or were managed conservatively. However, for men with high-grade tumours, survival rates were higher among those in the radical surgery group. Outcomes for men with intermediate grade tumours fell roughly mid-way between these extremes. Survival benefits were also reported for radical radiotherapy, but only among men with higher-grade tumours, and the effect diminished after five years.(B)

These results are only suggestive, not conclusive. They are not derived from randomised data and there are potential sources of bias. For example, the treatment given to patients who relapsed is not recorded: many probably had radiotherapy; and prostate cancer-specific death rates may not be reliable (see above). In addition, there was no adjustment for co-morbidity. Higher levels of co-morbidity would be expected in the conservative management group. Finally, there have been improvements in radiotherapy techniques, which may produce better outcomes in men who receive this form of treatment today.

Comparisons between radical treatment modalities: adverse effects

Studies of the impact of radical treatment on urinary and sexual function are consistent in reporting that surgery is more likely to lead to incontinence and/or impotence than radiotherapy.(B) Men who undergo surgery are less likely to be incontinent or impotent before treatment than those treated by radiotherapy, but are significantly more likely to become so afterwards. Bowel problems (proctitis) are common after external beam radiotherapy (EBRT), but are less severe with conformal radiotherapy than older methods of delivery.(A)

Surgery
Reported peri-operative mortality rates for radical prostatectomy range from 0.2% to 1.2%.(B) Reported rates for other adverse effects vary widely, but in general, they are considerably lower in case-series than in population studies.

A study of 1,291 men identified from the SEER registry revealed that only 32% of men had total urinary control (compared with 78% at baseline) and 44% were impotent (baseline 5%) two years after radical prostatectomy.(B) Much better results have been reported by expert surgeons, but it must be acknowledged that the patients included in such series may be carefully selected. Neither figures from case-series nor data derived from clinical trials can be regarded as realistic guides to outcomes in wider clinical practice.

Radiotherapy
Radiotherapy for localised prostate cancer can be delivered either by implantation of radioactive seeds (brachytherapy) or external beam. There is growing evidence that higher radiotherapy doses lead to better progression-free survival rates than lower doses, although the impact on overall survival is as yet unknown.(A) Two randomised studies have shown that conformal radiotherapy is associated with lower treatment morbidity than conventional radiotherapy; higher doses of radiotherapy can only be given when conformal radiotherapy is used.

Brachytherapy causes similar complications to external beam treatment and although adverse effects are believed to be less common, there have been no randomised trials to confirm this. Recent reports suggesting excellent outcomes are based on case-series and as such, may be seriously biased.

A US study of treatment given under Medicare two to three years after brachytherapy suggests that urinary obstruction was fairly common; 8.3% of the 2,124 men identified received surgery (usually trans-urethral resection of the prostate (TURP)) for bladder outlet obstruction.(B) Current techniques deliver lower doses of radiation to the urethra so this problem may occur less often; however, reliable information on outcomes is not available. The risk of incontinence associated with brachytherapy depends on previous surgery: TURP increases the incontinence rate from 1% to 12.5%,(B) and previous TURP is now regarded as a contra-indication to brachytherapy; but it is not clear whether brachytherapy increases the risk of incontinence if TURP is carried out subsequently. Reported impotence rates vary from zero to 38% and increase with time after treatment.(B)

Hormone therapy
The rate of progression of prostate cancer depends, in part, on the level of male hormones (androgens). This is the rationale for treatment with hormone manipulation using drugs, surgery

(orchidectomy), or both. Table 11 shows the main methods used, with the names of the drugs of each type available in the UK. There have been several meta-analyses of RCTs of different methods of manipulating androgen levels; these are consistent in showing that no form of medical treatment is more effective for disease control than orchidectomy.(A)

Table 11. Methods and agents used for hormone manipulation in prostate cancer

Method	Drug names	Advantages	Disadvantages
Surgical castration – orchidectomy	n/a	Low cost in long term. No treatment is more effective.	Irreversible; unacceptable to some men. Leads to loss of libido and symptoms similar to those of female menopause, such as hot flushes and osteoporosis.
"Medical castration" with LHRH or gonadorelin analogues	buserelin, goserelin, leuprorelin, triptorelin	Reversible. Probably as effective as orchidectomy	Loss of libido and hot flushes – adverse effects generally similar to surgery but wider range of symptoms. Initial stimulation of testosterone production can cause "tumour flare".
Anti-androgen treatment	bicalutamide, flutamide, cyproterone acetate (CPA)	Can be used with gonadorelin analogue to reduce tumour flare. Less depression of libido, fewer hot flushes than with other forms of treatment.	Loss of libido and hot flushes – adverse effects generally similar to surgery but wider range of symptoms. May be less effective than orchidectomy or LHRH analogues when used alone. Common adverse effects include breast pain and swelling (gynaecomastia) and risk of liver damage.

Hormone therapy begun immediately after diagnosis of locally advanced disease significantly reduces the rate of tumour progression and delays the onset of metastatic disease.(A) Hormone treatment can improve local disease control when used in combination with surgery when the cancer has invaded lymph nodes.(A) There is also accumulating evidence that adjuvant or neo-adjuvant hormone therapy, given with radiotherapy, can delay the progression of locally advanced disease. Some studies have reported survival benefits, but these may only be significant in specific sub-sets of patients.(A) It is not clear whether hormone therapy alone might be as effective as hormone treatment plus radiotherapy.

The first results of a very large study (n=8,113), assessing the effectiveness of adjuvant hormone therapy in combination with surgery, radiotherapy or watchful waiting, suggest that bicalutamide can significantly reduce the rate of tumour progression and delay the development of metastatic disease.(A) Survival data will not be available for some years.

This form of treatment can produce significant adverse effects, particularly loss of libido, impotence and hot flushes (see Table 11). Fewer patients withdraw from treatment because of adverse events with LHRH analogues than with non-steroidal anti-androgens (0-4% versus 4-10%). Treatment with an anti-androgen alone seems to have the least impact on libido and is least likely to cause hot flushes. Mono-therapy with an anti-androgen may be less effective for controlling the cancer and this type of drug can cause a variety of other adverse effects, particularly breast swelling and pain.(A)

Recent meta-analyses suggest that maximum androgen blockade – treatment with anti-androgens in addition to surgical castration or androgen suppression by pharmacological means – is unlikely to produce clinically significant survival benefits.(A) Maximum androgen blockade causes more severe adverse effects than monotherapy.(A)

Advanced disease

Radiotherapy for locally advanced and metastatic disease

External beam radiotherapy (EBRT) can help to relieve the symptoms of locally very advanced prostate cancer.(B) In addition, EBRT can reduce pain caused by bone metastases. Over 40% of patients experience at least 50% pain relief, and just under 30% can expect complete pain relief after one month. A single fraction is often effective; there appears to be little difference in efficacy between different fractionation schedules and doses.(A)

Strontium-89, a radioactive isotope which is taken up preferentially by bone, can reduce pain in men who have multiple painful bone metastases. It is as effective as EBRT for pain relief and may be more effective than local field EBRT for delaying the onset of pain at new sites, albeit at the expense of haematological toxicity.(A) One study suggests that it may improve survival when given with chemotherapy, but further research is needed to confirm this finding. Samarium-153 appears to offer similar benefits to Strontium-89 (A) but the two have not been directly compared in an RCT.

Palliative chemotherapy

The evidence on chemotherapy for men with advanced prostate cancer is poor, but it seems that some patients do benefit. This issue is being addressed by a number of ongoing trials using a range of agents including taxanes. One RCT found reduced pain scores after mitoxantrone/prednisolone chemotherapy in men with hormone-

refractory disease, and a second study suggested small but significant improvements in time to progression, with a trend towards improved quality of life.

There is some evidence suggesting that bisphosphonates may also be beneficial, but no definite conclusions can yet be drawn.

Current practice in the NHS

A survey of consultant urologists and general surgeons with an interest in urology was carried out in 1996 to gather information on the treatment of prostate cancer in the UK. Despite reminders, fewer than half responded, so the sample cannot be considered representative. Nevertheless, the findings give cause for concern for three main reasons: first, they suggest that many clinicians appear to hold exaggerated views of the value of radical treatment and are unduly reluctant to recommend active monitoring (observation); second, they reveal that some clinicians were giving ineffective forms of treatment; and third, few respondents referred symptomatic patients with metastatic disease to oncologists or palliative care specialists.

Radical treatment, usually radiotherapy, was favoured by consultants for the majority of patients – including those with T1 (localised) tumours and patients with asymptomatic disease. Observation was only the preferred option for patients aged 70 or more with well-differentiated early-stage disease. Even in this situation, 31% of respondents thought radical treatment would be more appropriate.

Taken as a whole, this survey suggests that radical treatments are recommended for many patients despite the paucity of evidence for their effectiveness or appropriateness.

D. Measurement

Structure

- Availability of access to brachytherapy at specified facilities.
- Availability of conformal radiotherapy.
- Systems for rapid access to treatment for potential spinal cord compression or fractures due to bone metastases.

Process

- Evidence that MDTs offer patients full information about treatment options and that they involve patients in decision-making about treatment, except if patients refuse opportunities for such involvement or suffer from such severe cognitive impairment that they are unable to understand treatment options.

- Evidence that patients with localised prostate cancer are given even-handed advice by the MDT on all treatment options.

- Evidence that the total annual number of radical prostatectomies plus cystectomies carried out for cancer by any team offering radical surgery is at least 50.

- Markers of quality of radical surgery, including the proportion of excised specimens with clear margins and blood transfusion requirements.

- Evidence that all forms of hormone therapy, including surgical castration, are discussed with patients.

- Evidence that patients given long-term hormone treatment are regularly reviewed by the treatment team.

- Evidence that patients have continuing access to a specialist nurse.

- Time between referral for palliative radiotherapy and treatment.

- Evidence that active monitoring includes regular PSA measurement.

- Evidence that men under active monitoring whose PSA levels show a sustained increase are given an opportunity to discuss treatment options with their MDT.

Outcome

- Short, medium and long-term survival rates of patients who undergo radical surgery, with information on cancer stage, co-morbidity, age and other features of case-mix. These data should be recorded for each surgeon.

- Short, medium and long-term survival rates of patients who undergo other types of treatment (including active monitoring), with information on case-mix.

- Major complication rates after surgery, radiotherapy or brachytherapy.

- Audit of quality of life, impotence, incontinence, bowel problems and hospital admissions one year after treatment (including patients under active monitoring).

- Audit of short-term and long-term adverse effects of treatment.

E. Resource implications

The resource consequences of the recommendations for the diagnosis and treatment of prostate cancer come under the Topic Areas for *Diagnosis and assessment* and *MDTs*. In addition, and not as a result of this guidance, the rising numbers of prostate cancer patients are likely to cost between £15.4 million and £43.8 million (see Appendix 1, *Economic implications of the guidance*), depending on the scale of the increase in incidence and the rate of PSA testing in the population at risk.

Testicular cancer

There are already specialist NHS services for the management of men with testicular cancer and outcomes are generally good, with 95% five-year survival rates even in metastatic disease. This is the only solid tumour type for which the vast majority of patients are cured. The recommendations below therefore define services which will build on, and improve, current practice.

A. Recommendations

A centralised service, described in outline in Topic 1 (*The urological cancer network and multidisciplinary teams*), is particularly appropriate for testicular cancer. Small and medium sized cancer networks should combine to offer a specialist service for a population base of two to four million. This supra-network service, based in selected cancer centres, would be expected to manage around 50-100 new patients each year.

Initial diagnosis and treatment (orchidectomy) should normally be carried out by a local urological cancer team; exceptions are discussed below. A full range of testicular prostheses should be available. All patients should be referred within 24 hours of surgery to designated specialist testicular cancer multidisciplinary teams (MDTs) for further assessment, and pathology should be reviewed by the specialist pathologist at the centre to which the patient is referred.

All patients should have computed tomography (CT) scans of the abdomen and pelvis. A CT scan of the chest is also necessary for patients with teratoma.

The following patients should be referred immediately (before orchidectomy) to the specialist MDT: those with obvious metastatic disease and very high tumour markers, lung metastases, or germ cell tumours in the mediastinum, lower abdomen (retroperitoneum) or brain.

Treatment of early stage and locally advanced disease

Seminoma

Adjuvant radiotherapy to the para-aortic region is standard practice in most UK centres, and should be discussed with all patients with stage I seminoma.

Alternative options, such as a single cycle of chemotherapy or surveillance (i.e. further treatment only if there is evidence of recurrence), should not be offered unless outcomes are meticulously monitored and patients receive careful counselling about the importance of early detection of recurrence.

Chemotherapy should be available for patients with more advanced disease, but radiotherapy may be appropriate when metastatic spread is confined to abdominal nodes of less than 5cm diameter.

Non-seminomatous germ cell tumours

After orchidectomy, patients with stage I malignant teratoma or mixed seminoma/teratoma without high risk features should normally be managed by surveillance by the specialist team, following a strict protocol. These patients should be selected after review of tumour pathology by the specialist pathologist who deals with testicular tumours at the centre. Surveillance is only appropriate if the patient is well motivated to return for follow-up and an effective service is provided.

Adjuvant chemotherapy, normally two courses of bleomycin/etoposide/cisplatin (BEP), should be discussed with patients when high risk features such as blood vessel or lymphatic invasion are found. However, as three cycles of BEP are usually adequate to treat patients who relapse, surveillance is an appropriate option. The specialist testicular cancer team should review every case when treatment has been completed.

Metastatic disease (seminoma or non-seminoma)

Chemotherapy

Men with metastatic testicular cancer should normally receive BEP chemotherapy. Those with intermediate or poor prognosis disease should be encouraged to participate in large multi-centre studies designed to help define the optimum treatment for this group of patients.

Management of residual masses

A substantial proportion of men who have undergone chemotherapy for metastatic tumours will have residual masses after treatment. Specialist review of radiology and pathology results is important to assess these masses, which may require surgical excision. This surgery should be undertaken in specialist centres where designated thoracic surgeons are available when needed. About 150 patients per year require highly specialised surgery, which is currently undertaken in at least 12 centres in England and Wales. This should be reviewed. It is doubtful whether centres which carry out fewer than 10 procedures per year have the necessary expertise to continue.

Sexual issues and fertility

The potential impact of testicular cancer on sexual function and fertility should be discussed with patients at the time of diagnosis. The treatment team should be alert to the possibility of psychosexual and body image problems and allow adequate time for discussion of such issues.

Sperm storage (cryopreservation) should be offered to all patients who may wish to father children. This should be available before chemotherapy or radiotherapy to the contralateral testis.

B. Anticipated benefits

Survival rates are currently high and the form of service described here is designed to maintain these good outcomes. The main focus of ongoing research into the management of testicular cancer is to identify treatment regimes that produce minimum toxicity whilst still achieving high cure rates.

C. Evidence

Note: The reliability and quality of evidence supporting the recommendations is graded A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Specialised treatment

There is consistent evidence that institutions that treat larger numbers of patients achieve better outcomes in testicular cancer (B) (see Topic 1, *The urological cancer network and multidisciplinary teams*). This suggests that specialised management is important for all forms of this disease.

Stage I seminoma

Reported cure rates for stage I seminoma are over 96%, irrespective of whether patients are managed by adjuvant radiotherapy or surveillance.(B)

Adjuvant radiotherapy

Prophylactic radiotherapy to the retroperitoneum and pelvis can be used to reduce the probability of relapse after orchidectomy. This can cause significant gastro-intestinal adverse effects, including pain, diarrhoea, nausea and vomiting, especially when delivered to a dogleg field.(A) In the longer term, patients who undergo radiotherapy face an increased risk of second malignancies, cardiovascular and renal disease. Radiotherapy to a smaller (para-

aortic) field is less toxic than dogleg radiotherapy and just as effective.(A) Treatment-related nausea and vomiting can be largely controlled with $5HT_3$ antagonists.(A)

Early results of a large (n=1,600) MRC study comparing one cycle of carboplatin chemotherapy with radiotherapy are expected to become available in 2003.

Stage I non-seminoma

Surveillance after orchidectomy

About a quarter of patients managed by surveillance will relapse and require salvage treatment; this is normally sufficient to eliminate the disease.(B)

Chemotherapy for advanced testicular cancer (seminoma and non-seminoma)

Prior to the introduction of platinum-based chemotherapy in the mid 1970s, most patients with metastatic testicular cancer died of the disease. Now, almost all are cured with combination chemotherapy (usually BEP), but these drugs can cause severe adverse effects. Recent research aimed to clarify the optimum chemotherapy regime and identify that which would maximise survival rates whilst minimising toxicity.

Three questions have dominated recent trials. The first was the necessity for bleomycin, which, although effective, can cause serious, sometimes fatal, lung damage; the second was whether carboplatin is an effective substitute for the more toxic cisplatin; and the third concerns the value of high-dose or high-intensity chemotherapy.

1. How important is bleomycin?

An ongoing systematic review of randomised controlled trials (RCTs) has concluded that bleomycin is beneficial despite its toxicity. Drug combinations which included bleomycin led to higher remission and survival rates than similar combinations without bleomycin ($p<0.01$).(A)

Some other drug combinations seem to be as effective as BEP and offer alternative options when necessary, but no combination has yet been demonstrated to be significantly more effective. Ifosfamide appears to be as effective as bleomycin but is also toxic.(A)

2. Is carboplatin an effective substitute for cisplatin?

Carboplatin and cisplatin are different forms of platinum chemotherapy, but cisplatin is the more toxic of the two. Studies comparing these drugs have found that cisplatin is more effective, reducing both relapse and deaths due to testicular cancer.(A)

3. Is more chemotherapy better?

Studies designed to establish which regimes offer the highest survival rates with least toxicity have defined the most effective range of doses and delivery periods. Maximising the effectiveness of chemotherapy requires the use of optimum doses over the optimum time-period (achieving optimum dose-intensity). Although some non-randomised studies have suggested that higher doses of drugs or the addition of extra chemotherapeutic agents may improve outcomes, there is no convincing evidence from randomised trials that high-dose chemotherapy is actually more effective than doses of BEP currently used in Europe.(A) Maintenance chemotherapy does not improve survival, it merely increases toxicity.(A)

Surgery for residual masses

A study of long-term outcomes among men treated with chemotherapy at the Royal Marsden Hospital between 1979 and 1986 reported that 31% of men were left with residual masses, 15% of which contained active cancer.(B) Surgery to remove such masses can lead to long-term survival, but may require complex procedures such as combined thoraco-abdominal surgery.(C)

Sexual issues and fertility

Testicular cancer is usually diagnosed when men are in the most sexually active phase of their lives, when many still look forward to fatherhood. Some have impaired semen quality before treatment, but cryopreservation of sperm before chemotherapy, radiotherapy or surgery for residual masses offers the chance of fatherhood after treatment.

Around a third of men who have been treated for testicular cancer suffer loss of desire or problems with sexual function.(B) The cause appears to be more often psychological than physical, although problems with ejaculation ("dry ejaculation") are reported most frequently in the research literature.(B)

D. Measurement

Structure

- Quality criteria for specialist germ cell tumour services have been defined by the Tri-Regional Germ Cell Tumour Working Group.

- Facilities for sperm banking.

Process

- Evidence that patients are fully informed and involved in decision-making about treatment.
- Time between diagnosis and initial treatment.

Outcome

- Five-year survival rates of patients who undergo radical treatment, with information on cancer stage, co-morbidity, age and other features of case-mix.
- Audit of short-term and long-term adverse effects of treatment.

E. Resource implications

No resource implications specific to the recommendations in this topic have been identified.

Penile cancer

A. Recommendations

Because penile cancer is so uncommon, its management should be formalised, with a degree of specialisation similar to that for testicular cancer. Specialised penis cancer multidisciplinary teams (MDTs) should be established jointly by two to four neighbouring networks. Each of these teams should serve a population base of four million or more and expect to manage a minimum of 25 new patients each year. The team should include members of the specialist urological cancer team who work in the cancer centre within which it is based, and it should also have access to expertise in plastic surgery.

Networks should agree referral protocols for patients with penile cancer. These should ensure that each new case is reviewed by a specialist penis cancer team, and that men who are likely to require lymph node dissection or reconstruction of the penis are treated by this team. Other forms of treatment may be carried out by specialist urological cancer teams which do not specialise in penile cancer, but the penis cancer MDT which reviews the case should remain responsible for overall management.

Surgery or radiotherapy may be used to treat early (stage I) penile cancer. The choice of treatment should be discussed with the patient in a meeting that includes a surgeon, clinical oncologist and specialist nurse.

The role of chemotherapy in the treatment of penile cancer is currently uncertain, but a trial of palliative chemotherapy should be considered for patients with metastatic disease.

B. Anticipated benefits

It is anticipated that increasing specialisation in the management of penile cancer will enhance the probability that patients receive appropriate treatment. At present, patients with early disease may be treated more aggressively than necessary, whilst those with more advanced disease and affected lymph nodes may not receive adequate treatment. This is important because men with lymphatic metastases can sometimes be cured by lymph node dissection.

C. Evidence

Note: The reliability and quality of evidence supporting the recommendations is graded A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

No randomised trials of any aspect of the management of penile cancer have been identified. All the studies in this field are observational in design and most are retrospective, so the research evidence is weak.

Amputation is the most common form of treatment used for penile cancer, but penis conserving therapy, using conservative surgery, radiotherapy (sometimes in combination with chemotherapy), brachytherapy, or laser treatment, is used for selected patients with localised tumours. Local failure rates may be higher than with amputation, but prompt use of salvage therapy for recurrence seems to produce similar survival rates.(B) Similarly, it is not known whether prophylactic lymph node dissection or radiotherapy is better than surveillance and salvage treatment for patients who develop recurrence. Randomised trials are needed to compare these ways of treating penile cancer.

The prognosis is poor for patients with metastatic penile cancer. Non-randomised studies suggest that the disease may respond to chemotherapy but it is not clear what the optimum therapeutic regime or schedule might be.(B)

D. Measurement

Structure

- Systems to ensure that patients are promptly referred to a penile cancer MDT.
- Effective links between the penile cancer MDT and local MDTs which may provide treatment for these patients.
- Availability of appropriate expertise in penis reconstruction.

Process

- Evidence that patients are fully informed and involved in decision-making about treatment.
- Use of lymph node dissection in patients at high risk of lymph node metastasis.

Outcome

- Five-year survival rates for all patients, with information on cancer grade and stage, co-morbidity, age and other features of case-mix.

- Audit of short-term and long-term adverse effects of treatment.

E. Resource implications

No resource implications specific to the recommendations in this topic have been identified. There may be some support costs associated with the formalisation of supra-network MDTs. These have not been calculated, as the numbers involved are small.

Bladder cancer

A. Recommendations

Superficial tumours

Patients with newly diagnosed, apparently superficial, tumours should be treated by complete trans-urethral resection (TUR), which should be carried out by designated urologists in local district general hospitals (DGHs). After recovery from resection, these patients should normally have a single instillation of chemotherapy (mitomycin or epirubicin) or glycine into the bladder (intravesical therapy). They should be allocated to one of the groups described below when the results of pathological review are available.

Lower-risk superficial cancer (pTa G1 or G2 or T1, G1 or G2)

About 50% of newly diagnosed patients have superficial tumours which carry a relatively low risk of progression after treatment but the majority of tumours will recur locally in the bladder. Guidelines for the frequency and timing of follow-up cystoscopy should be agreed and adopted throughout each network.

High-risk superficial cancer (pTa G3, or T1 G3 tumours, extensive, recurrent or multifocal G2 tumours, and carcinoma in situ)

These tumours are associated with higher risk of progression and death, and many patients are not receiving adequate treatment at present. Protocols for treatment and follow-up of patients with high-risk superficial tumours should be jointly agreed by the urological cancer multidisciplinary teams (MDTs) of each network and adopted throughout the network.

Although these patients may be treated – at least initially – by urologists who are members of local urological cancer teams, the options should be discussed with each patient in a joint meeting which includes a urologist, an oncologist and a nurse specialist who are also members of the MDT. The range of appropriate options may include intravesical treatment with bacillus Calmette-Guerin (BCG) or referral to the specialist urological cancer team for possible radical treatment. If the tumour fails to respond to BCG or recurs within a short time, radical treatment (normally cystectomy) should be offered. Patients with high-risk tumours should be encouraged, when

appropriate, to participate in randomised trials such as the MRC BS06 trial comparing radical radiotherapy with intravesical therapy.[61]

Muscle invasive tumours and locally advanced disease

All patients with invasive disease (pT2 and above) should be offered a joint meeting with a surgeon, oncologist, clinical nurse specialist, and palliative care specialist if appropriate, to discuss treatment options.

There is no clear-cut evidence for the overall superiority of surgery or radiotherapy; although surgery appears to offer better disease control, it has more severe adverse effects. There is an urgent need for a randomised trial comparing these treatment modalities.

Radical surgery

Radical surgery (cystectomy) should be available for patients with muscle-invasive tumours confined to the bladder. Although patients' general fitness should always be taken into account when radical treatment is being considered, age should not, of itself, be a bar to surgery.

Each network should agree clear guidelines on treatment and follow-up of bladder cancer which ensure that cystectomy is considered for patients with muscle-invasive or high-risk recurrent disease. Cystectomy is a complex operation which should be undertaken only by specialist surgeons working in cancer centres (see Topic 1, *The urological cancer network and multidisciplinary teams*). Ideally, all radical cystectomies undertaken in each network should be carried out by a single team.

Teams providing this form of surgery should carry out a cumulative total of at least 50 radical operations (cystectomies or radical prostatectomies) for bladder or prostate cancer per year. This level of work-load is currently unusual in the UK and a transition period is likely to be required for re-organisation of services before the criterion of 50 operations can be met. In the meantime, surgeons who currently carry out fewer than five cystectomies per year should refer patients to designated surgeons who will become more specialised in this type of surgery.

Surgical outcomes should be carefully audited and centres should aim to achieve 30-day mortality rates of 3.5% or less. Suitable patients should be offered bladder reconstruction or an alternative form of urinary diversion; facilities for reconstruction should be available wherever cystectomy is carried out.

[61] Details available by email: bs06@ctu.mrc.ac.uk

Adjuvant and neo-adjuvant chemotherapy

It is not yet clear whether adjuvant or neo-adjuvant chemotherapy is beneficial for patients with bladder cancer. Patients at high risk of progression, such as those with tumour in lymph nodes, should be encouraged to participate in trials of these forms of treatment. Chemotherapy should be initiated only by an oncologist member of the specialist MDT treating the patient.

Radical radiotherapy

Radical radiotherapy is appropriate for patients who are not sufficiently fit for surgery or who wish to avoid cystectomy. Patients who have had radiotherapy but would be sufficiently fit to undergo surgery should be followed up systematically and regularly so that salvage cystectomy can be offered if the tumour recurs. Neo-adjuvant radiotherapy – that is, lower dose radiotherapy given shortly before radical cystectomy – is not recommended outside the context of a formal clinical trial.

Metastatic disease

A trial of palliative chemotherapy should be considered for patients with metastatic disease; chemotherapy can relieve symptoms in patients who respond.

Short courses of radiotherapy should be available both for palliation of symptoms of advanced disease in the pelvis and for problems such as bone pain which may be caused by metastatic cancer. Services for management of bone metastases are discussed in the context of prostate cancer (see Topic 5, *Prostate cancer*).

B. Anticipated benefits

When these recommendations are implemented, patients with bladder cancer will be more likely to receive effective treatment – particularly cystectomy and bladder reconstruction when appropriate. This will improve both survival time and quality of life among patients with invasive tumours.

C. Evidence

Note: The reliability and quality of evidence supporting the recommendations is graded A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Superficial cancer

Intravesical therapy

There is strong evidence from a series of meta-analyses of randomised controlled trials (RCTs) that intravesical therapy (bladder irrigation given after trans-urethral resection) delays recurrence of superficial bladder cancer. Intravesical chemotherapy reduces the risk of local recurrence by around 50% for one to two years after initial treatment, and the proportion of patients who remain disease-free at eight years is increased by 8%.(A)

Intravesical treatment with BCG also reduces tumour recurrence, and may be more effective than intravesical mitomycin C (the chemotherapeutic agent used most frequently) for higher-risk patients.(A) There is currently no evidence to show that intravesical treatment improves long-term survival and no significant differences have been found between agents in effects on disease progression or survival.(A)

The most common side-effect of intravesical treatment with chemotherapeutic agents or BCG is local inflammation in the bladder or urethra, leading to problems with urination such as frequency and urgency, haematuria and pain. Systemic adverse effects such as 'flu-like symptoms and fever are particularly associated with BCG and can be serious.(A)

Results from an MRC RCT suggest that post-operative treatment with glycine, which is not toxic, can also produce sustained benefits, reducing recurrence rates at five years by 6% (from 62% to 56%, p=0.05).(A) There have been no randomised trials comparing glycine with other agents.

Follow-up of patients treated for superficial bladder tumours

Follow-up may involve cystoscopy and/or ultrasound imaging of the bladder. There is no reliable evidence to show what the most appropriate follow-up strategy might be. Small-scale observational studies have reported that most recurrences occur within two years of initial treatment.(B)

An RCT comparing two follow-up schedules for patients treated for superficial bladder cancer found no difference in clinical outcomes.(A) A cost-effectiveness study reported that frequent cystoscopy produced no clinically meaningful advantage over less frequent follow-up, and that significant financial savings could be made by reducing follow-up. It was estimated that each cystoscopy led to one additional day of life.

Muscle-invasive disease

Surgery (radical cystectomy)

Surgeons with a special interest in uro-oncology working in NHS hospitals have reported peri-operative mortality rates of under 2% after cystectomy. Recent audit data from Newcastle show a post-operative death-rate of just 1.3% in a series of 300 consecutive patients who underwent cystectomy between 1999 and 2001.(B)

These results compare favourably with those reported by international centres of excellence, but they are unlikely to be representative of outcomes in most NHS hospitals. Fewer than 5% of hospitals which undertake cystectomy do as many in a year as Newcastle. Few surgeons, therefore, are able to develop the level of skill required to achieve such a low mortality rate in the context of current service arrangements. Although there is no clear evidence of a volume effect in outcomes after radical cystectomy, there is for radical prostatectomy (see Topic 5, *Prostate cancer*, and Topic 1, *The urological cancer network and multidisciplinary teams*), and for many other types of radical surgery for cancer.

In a US series which included over 1,000 patients with muscle-invasive bladder cancer who underwent radical cystectomy with iliac lymphadenectomy, the peri-operative death-rate was 3% and the overall survival rate was 66% at five years.(B) Whilst these results are impressive, it is likely that the patients were carefully selected.

Studies from the UK and elsewhere have demonstrated that there is no relationship between patients' age and mortality or morbidity associated with cystectomy. Co-morbidity and tumour grade, rather than age, are the important predictors of outcome.(B)

Radiotherapy

Radical radiotherapy can lead to long-term survival in patients with invasive bladder cancer.(B) There is currently no clear evidence to show whether radiotherapy is more or less effective than surgery for preventing disease progression and death from bladder cancer when either treatment modality could be used. There is evidence suggesting differences in outcome between these modalities, but some studies favour surgery whilst others do not. This could reflect wide variability between centres in techniques, skilled staff, and equipment.

A retrospective study of patients treated in Yorkshire between 1993 and 1996 found that, despite a 30-day death rate of 3%, three-month mortality rates were lower after radiotherapy (n=302) than after surgery (n=96), at 1.4% versus 8.3%, respectively. Five-year survival rates were similar, at 37.4% in the radiotherapy group (with or without salvage cystectomy), versus 36.5% after initial surgery. Another UK study (n=120) reported an overall median survival time of five years after radical radiotherapy.(B)

In patients whose disease has advanced beyond the bladder itself, surgery may not be an option. Radiotherapy has the advantage of leaving the bladder intact but can cause other adverse effects; one study of morbidity after radical radiotherapy found that 8% of patients had proctitis and 4% had cystitis a year later. The consequences of surgery may be more distressing for some patients, however; a study published in 1989 reported that all male patients who had undergone cystectomy were impotent, compared with 36% of those who had had radiotherapy; in addition, patients treated by surgery were more likely to complain of fatigue six months after treatment.(B)

A meta-analysis of three RCTs comparing pre-operative radiotherapy plus radical surgery with radical radiotherapy followed by salvage cystectomy for recurrence, suggests that patients whose primary treatment is surgery are almost twice as likely to become long-term survivors as patients treated by radical radiotherapy.(A) Mean five-year survival rates were 36% among patients treated by pre-operative radiotherapy and radical cystectomy and 20% in the radical radiotherapy/salvage cystectomy group. Another meta-analysis, of four RCTs, found that pre-operative radiotherapy followed by surgery does not improve survival, compared with surgery alone.(A)

The studies in these meta-analyses involved less sophisticated treatment techniques than are available today, and it is possible that the findings would be different now. A well-designed RCT comparing modern surgery with modern radiotherapy (with or without neo-adjuvant chemotherapy) is badly needed.

Chemotherapy

The effectiveness of chemotherapy is uncertain. Meta-analysis of individual patient data from four RCTs shows no significant survival benefit from neo-adjuvant or concurrent chemotherapy in combination with radical surgery or radiotherapy for locally advanced bladder cancer.(A) A more recent European study of neo-adjuvant cisplatin methotrexate vinblastine (CMV) chemotherapy also shows no significant benefit.(A) By contrast, a recent North American study of methotrexate, vinblastine, doxorubicin and cisplatin (MVAC) followed by cystectomy has reported significantly higher survival rates in the chemotherapy arm, with estimated median survival times of 6.2 years in the MVAC arm, compared with 3.8 years after cystectomy only: a hazard ratio 0.74 (95% CI: 0.55 to 0.99, p=0.027).(A) The research evidence on adjuvant chemotherapy is also inconclusive. Randomised trials are in progress and should be supported.

Advanced disease

Radiotherapy

Radiotherapy can provide effective palliation for symptoms of locally advanced or metastatic bladder cancer. Two-thirds of symptoms were reported to be alleviated for a median period of nine months after

treatment with 35Gy in 10 fractions or 21Gy in three fractions. These two radiotherapy schedules were equally effective.(A)

Chemotherapy

Advanced bladder cancer can respond to chemotherapy but chemotherapy has not been compared with best supportive care in a randomised trial. The combination of cisplatin and gemcitabine is relatively well tolerated and appears to be as effective as the more toxic regimen, MVAC;(A) however, no randomised trial has reported response rates over 65% with any drug or combination, and median survival times are generally less than one year.(A)

Treatment in the NHS

Treatment in the NHS is currently fragmented and it appears that the level of expertise for effective management of invasive cancers is not available for the majority of patients. Few urologists treating patients with invasive bladder cancer work with oncologists.(B) Furthermore, the surgical management of bladder cancer does not appear to be adequate. Figures derived from hospital episode statistics (HES) and British Association of Urological Surgeons (BAUS) data suggest that fewer than half of the patients who might benefit from cystectomy actually receive this operation (see Appendix 1, *Economic implications of the guidance*).

A study of the management of muscle-invasive bladder cancer in the South West Region in 1989 and 1993 revealed that 46% of patients received no definitive treatment for their tumours. Just 12% of patients with T2 tumours and 19% with T3 tumours underwent cystectomy; the treatment most frequently used was radiotherapy (radical or palliative). Significantly more patients with T2 tumours received no definitive treatment than patients with T3 tumours, which suggests that many with T2 tumours, in particular, had sub-optimal treatment. There were no differences in co-morbidity between patients who received different types of treatment or no treatment at all, but their ages were significantly different: median ages of those who had primary cystectomy, radical radiotherapy and no definitive treatment were 64 years, 69 years, and 76 years, respectively.(B)

D. Measurement

Structure

- Network-wide protocols for treatment and monitoring of patients with bladder cancer; these protocols should specify intervals for follow-up cystoscopy after different stages and grades of disease.
- Access to an MDT which includes surgeons with specialist expertise in cystectomy and bladder reconstruction.

- Systems for provision of rapid access to short courses of palliative radiotherapy.

Process

- Evidence that patients are informed and involved in decision-making about treatment, unless they refuse opportunities for such involvement or they suffer from such severe cognitive impairment that they are unable to understand treatment options.

- Evidence that patients with muscle-invasive or recurrent cancer are given even-handed advice by the MDT on radical treatment options.

- Evidence that each surgeon responsible for cystectomy does a large enough number of these operations each year for meaningful audit of individual outcomes.

- Evidence that the total annual number of cystectomies plus radical prostatectomies carried out for cancer by any team offering cystectomy is at least 50.

- Markers of quality of radical surgery, including the proportion of excised specimens with clear margins and blood transfusion requirements.

- Proportion of patients who receive each form of treatment, stratified by tumour stage and grade, age and co-morbidity.

- Time between diagnosis and initial treatment.

Outcome

- Audit data demonstrating peri-operative mortality rates of <4% after cystectomy.

- Major surgical complication rates within three months of operation.

- Five-year survival rates for all patients, with information on cancer grade and stage, co-morbidity, age and other features of case-mix.

- Audit of short-term and long-term adverse effects of treatment.

E. Resource implications

The estimated costs of centralisation of radical cystectomy are combined with prostatectomy (see Topic 1, *The urological cancer network and multidisciplinary teams*).

Kidney cancer

The information below is primarily concerned with renal cell cancer. Patients with less common forms of kidney cancer should be referred to specialist urological cancer teams for treatment.

A. Recommendations

All patients who are sufficiently fit to undergo surgery should be offered radical nephrectomy (except those with small tumours – see below); this should be considered even when there is metastatic disease. Usually, nephrectomy is a relatively straightforward procedure which can be safely carried out by the local urological cancer team. Although surgery is normally the only treatment necessary for localised tumours, oncologists should be involved in discussions about the management of all patients.

Probably 80% of patients with kidney cancer can be managed by local cancer teams, but adequate assessment using appropriate imaging-computed tomography (CT) or magnetic resonance imaging (MRI) – is essential to identify those who should be referred for specialist treatment at cancer centres. (See Topic 2, *Diagnosis and assessment.)*

Patients who should be managed by specialist urological cancer teams at cancer centres include the following:

- Those whose tumours have, or may have, invaded the renal vein or vena cava, or which may involve the heart;
- Those with limited metastatic disease which might be amenable to resection;
- Those who have bilateral disease or who will require dialysis;
- Patients with von Hippel-Lindau disease or hereditary papillary tumours.

Patients with small tumours for whom nephron-sparing surgery may be possible, should be discussed with a surgeon from a specialist urological multidisciplinary team (MDT). Referral to the centre is likely to be appropriate for these patients.

Treatment with immunotherapeutic agents (normally interferon alpha) should be available for patients with metastatic kidney cancer. Such therapy should be given by specialist oncologists with experience of its use, preferably in the context of a well-designed clinical trial. Patients should be encouraged to participate in open discussions with members of the MDT about the balance of potential harm and benefit associated with different therapeutic options.

When a patient has not undergone surgical resection, the nature of the tumour should be confirmed by biopsy before anti-cancer therapy is offered.

B. Anticipated benefits

Surgery is usually curative in early disease, and may be curative even when there is limited metastatic disease. Nephrectomy may also improve outcomes in more widespread metastatic disease. Immunotherapy can increase survival time in metastatic disease and offers the hope of complete remission for a small minority (around 5%) of patients.

C. Evidence

Note: The reliability and quality of evidence supporting the recommendations is graded A, B and C, where A is the strongest evidence. The grading taxonomy is explained in Appendix 2.

Surgery

There have been no randomised studies comparing partial nephrectomy with radical nephrectomy, but evidence from observational studies suggests that some patients survive for many years after partial nephrectomy without evidence of recurrent cancer.(B)

Radical nephrectomy is often curative in early stage kidney cancer; non-randomised studies report relapse rates of 20-30%.(B) It also has a palliative role, reducing symptoms, thereby presumably improving quality of life. In some patients, surgical resection of a solitary metastasis after radical nephrectomy can lead to long-term disease control.(B) Radical nephrectomy, carried out prior to treatment with interferon, may improve survival even in metastatic kidney cancer; however, few patients in this situation are sufficiently fit to undergo major surgery.

Systemic therapy

Kidney cancer rarely responds to chemotherapy and few patients benefit from it. Adjuvant immunological therapies such as interferon alpha have also been found to be ineffective in early disease.

In patients with advanced or metastatic disease, however, interferon alpha can increase survival time despite adverse effects – most often a 'flu-like syndrome – in the majority of patients.(A) The strongest evidence for the effectiveness of interferon comes from two randomised trials. One compared interferon with medroxyprogesterone acetate in 335 patients and found that those in the interferon group lived 2.5 months (median) longer (p=0.017).(A) The second trial, which randomised 160 patients to vinblastine alone or in combination with interferon-alpha, reported median survival times of 38 weeks with vinblastine alone, compared with 68 weeks with both agents together (p=0.049).(A)

Around 5% of patients experience complete, and sometimes long-lasting, responses to treatment with interferon alpha or interleukin-2.(A) However, spontaneous remission is known to occur occasionally in untreated patients.(B)

A triple regime which includes interleukin 2, fluorouracil (5-FU) and interferon has been linked with the highest reported response rates both in non-randomised studies and in a randomised controlled trial in which it was compared with tamoxifen.(A) In the latter study, median survival in the triple-therapy group was 42 months, compared with 14 months in the tamoxifen group (p<0.04). However, toxicity problems increase when additional agents are given in combination with interferon, and other studies have failed to confirm that improved response rates are associated with enhanced survival.(A)

Research into a variety of forms of treatment, particularly combination therapies based on biological agents, is continuing.

D. Measurement

Structure

- Systems to ensure that appropriate patients are promptly referred to the specialist MDT.
- Availability of immunotherapy for patients with metastatic disease.

Process

- Evidence that patients are fully informed and involved in decision-making about treatment.

Outcome

- One and five-year survival rates for all patients, with information on cancer grade and stage, co-morbidity, age and other features of case-mix.

- Audit of short-term and long-term adverse effects of treatment.

E. Resource implications

No resource implications specific to the recommendations in this topic have been identified.

Appendix 1

Economic implications of the guidance

The cost implications of the urological cancer guidance can be divided into five main categories, listed below. Three are general categories of relevance to all urological cancers, while the last two are site-specific.

- Multidisciplinary teams (MDTs)
- Centralisation
- Specialist nurses
- Prostate cancer (incidence and other costs)
- Bladder cancer (diagnostic testing and treatment)

The increase in costs for the diagnosis and treatment of patients with kidney, testicular and penile cancers is likely to be small.

Multidisciplinary teams

Multidisciplinary team working is intended to ensure that patients benefit from the expertise of a range of specialists for their diagnosis and treatment, and that care is given according to recognised guidelines. For some cancers MDTs are well established in most Trusts, but for urological cancers even the concept of MDTs is not well-accepted in all Trusts.

While most centres hold regular MDT meetings, many have insufficient time to review all patients. At units the problems are more severe, with lack of administrative support being a particular problem. Both units and centres struggle to get a full team together, with the lack of availability of radiologists, pathologists and oncologists a special problem, exacerbated at units where they may only have visiting clinicians for a session every two weeks. The cost of ensuring that all MDTs have a co-ordinator, and of additional staff time for MDT meetings is estimated to be an additional £6.4 million per year.

Centralisation

The guidance recommends some centralisation of services, in particular requiring that MDTs which undertake radical prostatectomy and cystectomy should perform a combined total of at least 50 operations per year. Ideally there should be only one team per network, covering a population of at least one million people, undertaking this type of surgery. Analysis of the data shows that this is a radical change from current practice.

To estimate the effect of greater specialisation of services for radical prostatectomy and cystectomy, an analysis was undertaken of the current (1999/2000) number of operations by hospital, network and region, and an estimate made of the proportion of work that will have to move from units to centres in each network in order to fulfil the requirements of the guidance. Different configurations are possible, so maximum and minimum scenarios were developed to cover the likely range. The central cost estimate is £4.4 million per year, with a range of £3.8 to £5.0 million.

The impact on Trusts taking on the work may be significant. Typically the number of prostatectomies and cystectomies they will undertake will more than double (from around 35 per year) as a result of the guidance, but increasing incidence of prostate cancer and more aggressive treatment of bladder cancer may also considerably increase the demand for these operations. This may mean that they have to increase their capacity by a factor of four or five, with knock-on effects on demand for theatre capacity and special care nursing.

Specialist nurses

The guidance emphasises the need for improved information and support for urological cancer patients, and the central role that nurse specialists should play in delivering more patient-centred care.

The current provision of nurse specialists is patchy. There are several specialist nurses who are providing the levels of support indicated in the guidance. However, some are stretched very thinly, being solely responsible for several hundred cancer patients. Audit data from the North West Region suggests that many urological cancer patients do not receive counselling from a specialist nurse, and that consequently they may lack significant information about their treatment. The recent Commission for Health Improvement and Audit Commission (CHI/AC) report[1] indicates that at the time of the survey (winter 2000/2001) only around 50% of Trusts providing a urological cancer

[1] Commission for Health Improvement, The Audit Commission. *NHS Cancer Care in England and Wales*. London; 2001. Report No: 1.

service had a nurse specialist. The situation is changing rapidly with nurses being appointed, so for the cost estimate it is assumed that it is only 30% of Trusts that still require a specialist nurse. For the 70% of Trusts that are assumed to already have at least one nurse it will be assumed that on average they need 30% more nursing resource, on the basis that around 30% of specialist urological cancer nurses reported severe time constraints on the service that they could provide.[1]

On the basis of these assumptions, around 80 more nurse specialists will be required, at an annual cost of £2.68 million. If it is assumed that these additional nurses will need to complete a post-registration diploma in oncology nursing (ENB 237) the training cost is £0.32 million.

Prostate cancer

Incidence

The greatest increase in the costs of caring for urological cancer patients over the next few years is likely to arise from the increasing incidence in prostate cancer, rather than in implementing the guidance. This probable increase in incidence is expected as a consequence of many more men being screened for prostate cancer with the prostate specific antigen (PSA) test. Many urologists believe that it is not just plausible, but probable, that incidence rates in the UK will rise to American levels. Whether incidence will really more than double, and how fast incidence will increase, is very difficult to predict. Currently there is very little hard evidence of an increase in incidence, but the latest national figures are for 1998. The 1998 figures do show an increase of 12.6% over 1997, which may signal the start of an upward trend, but could be owing to statistical variation.[2,3,4] However, there is evidence that PSA testing increased during the late 1990s, and is likely to have increased further. Urologists report seeing many more patients with possible prostate cancer, and expect to see even more in the future.

Given this uncertainty, three different scenarios were devised. The highest increase assumes that there has been a steady increase from 1998 to 2001, but that incidence will then rise more steeply to reach American levels by 2004. This would give an incidence of 45,000 for England and Wales, compared to approximately 20,500 in 1998. The low scenario is based on a continuing steady increase from 1998 to

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2 Quinn M, Babb P, Brock A, et al. *Cancer trends in England and Wales 1950-1999.* London: Stationery Office, 2001.

3 Office for National Statistics. *New cases of cancer diagnosed in England, 1998.* ONS, 2002. Available from: http://www.statistics.gov.uk

4 Welsh Cancer Intelligence and Surveillance Unit. Personal Communication. 2002.

2004, with the central scenario based on mid-point estimates for 2001 and 2004. These scenarios give a range of additional costs of £15.4 to £43.8 million per year, with a central estimate of £28.2 million.

Other costs

The guidance will result in more patients having magnetic resonance imaging (MRI) prior to radical treatment - not currently routine practice for all patients. This is likely to cost an additional £0.4 million per year. This cost should be more than offset by the reduction in bone scans. Scans are rarely useful for patients with a PSA level of less than 10ng/ml and Gleason score less than 8, but audit data suggests that a third of patients with localised cancer having a scan fall into this category. The potential annual cost saving is £0.5 million.

The guidance encourages the use of conformal radiotherapy where possible. Conformal radiotherapy requires more consultant oncologist, radiographer and medical physicist time than conventional external beam radiotherapy. Assuming that machines are provided, the ongoing additional cost of providing all patients with conformal radiotherapy is modest, at £0.2 million per year. This total annual cost assumes cost savings resulting from the phasing out of the use of the low melting point alloy method of providing conformal radiotherapy, which is more laborious, and therefore more expensive, than conformal radiotherapy with multileaf collimators.

Bladder cancer

Audit and HES data show that patients are being more actively treated for bladder cancer than a few years ago, but that there is still a need for further improvement. Increased treatment costs will be incurred as a result of the guidance. Additional intravesical chemotherapy for superficial cancers will cost £2.0 million, and an additional 850 cystectomies a year may be required, at a cost of £3.9 million.

Cost Summary

(All costs in millions of pounds per year)

Multidisciplinary teams		
MDT co-ordinator for all units and additional consultant sessions	£3.56	
Additional costs of staff time at units and centres	£2.84	
Subtotal		**£6.40**
Centralisation – central		**£4.39**
Low scenario	£3.79	
High scenario	£4.98	
Patient-centred care (specialist nurses)		**£2.68**
Prostate cancer		
Potential increase in prostate cancer incidence		**£28.19**
Low scenario	£15.40	
High scenario	£43.84	
MRI prior to radical treatment		**£0.37**
Low scenario	£0.23	
High scenario	£0.40	
Conformal radiotherapy for radical treatment		**£0.16**
Low scenario	£0.10	
High scenario	£0.17	
Bone scans		**-£0.53**
Low scenario	-£0.34	
High scenario	-£0.58	
Bladder cancer		
Diagnosis	£0.28	
Treatment	£5.93	
Subtotal		**£6.21**
Total		**£47.87**
Range		**£34.47 - £64.10**

A1

Appendix 2

How this guidance manual was produced

The Manuals in this series are intended to guide health organisations (strategic health authorities, primary care Trusts, cancer networks, and Trusts), their managers and lead clinicians in improving the effectiveness and efficiency of services for patients with cancer. The information and recommendations in the Manual are based on systematic reviews of the best available evidence on diagnosis, treatment and service delivery. This evidence is assessed by experts and the recommendations are the product of extensive discussion with leading clinical specialists. The production process is described briefly below; more detail is available in earlier guidance Manuals in the series.

The production process begins with a two-day residential event where proposals for improving services for patients with cancer of a specific site are generated. A large group of relevant health care professionals, people with personal experience of the particular type of cancer being considered, health care commissioners and academics from around the country, meet to put forward structured proposals based on their experience and knowledge of the research literature. All proposals share a common structure and are intended to improve outcomes for patients. These proposals are then sent to referees, including clinicians, academics, representatives of health authorities, the Department of Health, patient organisations, and relevant charities, many of whom make detailed comments and suggestions. Systematic reviews of the research literature, designed to evaluate the proposals, are then carried out or commissioned by the NHS Centre for Reviews and Dissemination (CRD) at the University of York.

This process culminates in the production of two large sources of information, one with a practical or operational focus, and the other containing detailed research evidence on effectiveness. The guidance draws on both these sources, with added input from commissioners, patients, and experts in the particular fields. The writing of the guidance manual is overseen by an editorial group chaired by Professor Bob Haward, accountable to the National Cancer Guidance Steering Group. The writing is undertaken by Dr Arabella Melville, in conjunction with CRD.

Complementary research, designed to quantify the potential cost of major changes in services, is carried out by the School of Health and Related Research at the University of Sheffield. This work involves literature searching, interviews with clinicians and managers, and analyses of costs.

Evidence grading

The reliability and quality of evidence which supports the recommendations in the guidance manual is graded throughout the document. The grades are as follows:

A. Evidence derived from randomised controlled trials or systematic reviews of randomised trials.

B. Evidence from non-randomised controlled trials or observational studies.

C. Professional consensus.

The quality of research evidence forms a continuum and there is overlap between these categories. Most of the published research on cancer focuses on clinical evaluations of treatment; little direct research has been carried out on the organisation and delivery of services, issues on which randomised controlled trials (categorised here as the highest quality evidence) may not be feasible. Research designs which might be regarded as of relatively poor quality for evaluating a clinical intervention may therefore be the most reliable available for assessing the organisational issues.

The systematic reviews used to inform the Manual are summarised in the document *Improving Outcomes in Urological Cancers: The Research Evidence*. This document includes details of all the studies to which the Manual refers. It is available on the CD-rom provided with this Manual, and can be purchased in printed format as a CRD report (email: crdpub@york.ac.uk, tel: 01904-433648).

Appendix 3

People and organisations involved in production of the guidance

3.1 National Cancer Guidance Steering Group

3.2 Participants in the proposal generating event

3.3 People/organisations invited to comment on original proposals

3.4 Researchers carrying out literature and economic reviews

3.5 Members of focus groups

Guidance synthesis and writing

Ms A Eastwood	Senior Research Fellow, NHS Centre for Reviews and Dissemination, University of York
Mr A Flynn	Research Fellow NHS Centre for Reviews and Dissemination, University of York
Professor J Kleijnen	Director, NHS Centre for Reviews and Dissemination, University of York
Dr D Lister-Sharp	Research Fellow, NHS Centre for Reviews and Dissemination, University of York
Dr A Melville	Independent Consultant

assisted by members of the National Cancer Guidance Steering Group, together with:

Mr N Clarke, Consultant Urologist, Hope Hospital, Salford
Dr S Harland, Consultant Medical Oncologist, Middlesex Hospital, London
Dr P Harnden, Consultant Urological Pathologist, St James's University Hospital, Leeds
Professor A Horwich, Professor of Clinical Oncology, Royal Marsden Hospital, Sutton
Professor J Husband, Professor of Diagnostic Radiology, Royal Marsden Hospital, Sutton
Professor M Mason, Professor of Clinical Oncology, Velindre Hospital, Cardiff
Professor D E Neal, Professor of Surgery, University of Newcastle Medical School, Newcastle upon Tyne

People/organisations invited to comment on drafts of the guidance

National Cancer Guidance Steering Group
Focus groups
Various professional organisations
Department of Health
NICE Stakeholders

Economic reviews

School of Health and Related Research, University of Sheffield

Project support

The Northern and Yorkshire Cancer Registry and Information Service

Appendix 3.1

Membership of the National Cancer Guidance Steering Group

Chairman

Professor R A Haward	Professor of Cancer Studies, University of Leeds

Vice Chairman

Professor M Richards	Sainsbury Professor of Palliative Medicine, St Thomas' Hospital, London and National Cancer Director

Members

Dr J Barrett	Consultant in Clinical Oncology and Clinical Director, Four Counties Cancer Network
Mrs G Batt	Section Head, Cancer Policy Team, Department of Health, Wellington House
Mr A Brennan	Director of Operational Research, School of Health and Related Research, University of Sheffield
Ms A Eastwood	Senior Research Fellow, NHS Centre for Reviews & Dissemination, York
Dr J Hanson	Cancer Services Project Co-ordinator, Welsh Office
Dr G Harding	GP and Medical Director, St John's Hospice, Doncaster
Professor J Kleijnen	Director, NHS Centre for Reviews & Dissemination, York
Professor P Littlejohns	Clinical Director, National Institute for Clinical Excellence
Professor R E Mansel	Chairman, Division of Surgery, University of Wales College of Medicine, Cardiff
Dame G Oliver	Director of Service Development, Macmillan Cancer Relief
Mrs V Saunders	Manager, Northern and Yorkshire Cancer Registry and Information Service
Dr J Verne	Consultant in Public Health Medicine, Department of Health South and West Regional Office

Appendix 3.2

Participants in the urological cancers proposal generating event

Mr M Aitchison	Consultant Urologist, Gartnavel General Hospital, Glasgow
Dr I D Ansell	Consultant Histopathologist, Nottingham City Hospital
Mr R C Beard	Consultant Urologist, Worthing Hospital
Dr A Benghiat	Cancer Lead Clinician, Leicester Royal Infirmary
Ms J Booker	Macmillan Urology Nurse Specialist, Christie Hospital, Manchester
Dr D Bottomley	Consultant in Clinical Oncology, Cookridge Hospital, Leeds
Mr S Brewster	Consultant Urologist, Churchill Hospital, Oxford
Mrs M Bullen	Director of Cancer Nursing, Maidstone Hospital, Kent
Mr M Carr	Patient
Ms E Cheesman	Senior Information Nurse, CancerBACUP
Mr T Christmas	Consultant Urologist, Charing Cross Hospital, London
Dr P Clark	Consultant in Medical Oncology, Clatterbridge Centre for Oncology
Dr R Clements	Consultant Radiologist, Royal Gwent Hospital, Newport
Dr S Closs	Consultant in Palliative Medicine, Morriston Hospital, Swansea
Dr D Cochlin	Consultant Radiologist, University Hospital of Wales, Cardiff
Dr D Dearnaley	Consultant in Clinical Oncology, The Royal Marsden Hospital, Sutton
Ms J Farrell	Urology Nurse Specialist, Rotherham District General Hospital
Mr D Fawcett	Consultant Urologist, Battle Hospital, Reading
Mr R Firth	Patient
Mr M V P Fordham	Consultant Urologist, Royal Liverpool University Hospital

Mr T Gittings	Patient
Dr J Graham	Consultant in Clinical Oncology, Bristol Oncology Centre
Dr K Grigor	Consultant Pathologist, Western General Hospital, Edinburgh
Ms C Grose	Urology Nurse Practitioner, Stepping Hill Hospital, Stockport
Dr J Halpin	Consultant/Senior Lecturer in Public Health Medicine, East & North Hertfordshire Health Authority
Dr P Harnden	Consultant Urological Pathologist, St James's University Hospital, Leeds
Ms S Hunton	Director, Bradford Cancer Support Centre
Dr N James	Consultant in Clinical Oncology, Queen Elizabeth Hospital, Birmingham
Dr M Jefferson	Consultant in Palliative Medicine, University of Wales College of Medicine, Cardiff
Dr J Joffe	Consultant in Medical Oncology, Huddersfield Royal Infirmary
Mr M Khan	Patient
Dr M King	Consultant Radiologist, The Royal Marsden Hospital, London
Ms S Lynch	Radiotherapy Section Manager, Clatterbridge Centre for Oncology
Dr A Marks	Consultant in Palliative Medicine, Dellwood Community Hospital, Reading
Professor M Mason	Professor of Clinical Oncology, Velindre Hospital, Cardiff
Dr G Mead	Consultant in Medical Oncology, Royal South Hants Hospital, Southampton
Dr J Melia	Project Co-ordinator, Cancer Screening Evaluation Unit, Institute of Cancer Research, Sutton
Mr L Moffat	Consultant Urologist, Aberdeen Royal Infirmary
Dr L N S Murthy	Consultant Radiologist, Freeman Hospital, Newcastle upon Tyne
Professor D E Neal	Professor of Surgery, University of Newcastle Medical School, Newcastle upon Tyne
Dr P Norris	GP, Kingston upon Thames
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Dr D Rickards	Consultant Radiologist, The Middlesex Hospital, London
Dr J T Roberts	Consultant in Clinical Oncology, Newcastle General Hospital, Newcastle upon Tyne

Dr E A Scott	Director of Public Health, Leeds Health Authority
Professor P Selby	Professor of Cancer Medicine, St James's University Hospital, Leeds
Mr C Sloane	Patient
Dr N Summerton	Clinical Senior Lecturer in Primary Care Medicine, University of Hull
Dr G Tanner	GP, Bridgwater
Dr J Thomas	Director of Public Health, Sunderland Health Authority
Mr S Vesey	Consultant Urologist, Southport and Formby District General Hospital
Mrs S Weatherall	Patient
Dr J Wilkinson	Director, Northern & Yorkshire Public Health Observatory
Dr C Wolfe	Reader in Public Health Medicine, Guy's, King's and St Thomas' School of Medicine, London

Facilitated by:

Dr J Barrett	Consultant in Clinical Oncology and Clinical Director, Four Counties Cancer Network
Professor R A Haward	Professor of Cancer Studies, University of Leeds
Professor J Kleijnen	Director, NHS Centre for Reviews and Dissemination
Professor M A Richards	Sainsbury Professor of Palliative Medicine, St Thomas' Hospital, London and National Cancer Director

Appendix 3.3

Referees of the urological cancers proposals

The guidance was subject to the NICE consultation process (see website www.nice.org.uk for details)

The individuals listed below were also invited by the Developer to act as referees (347) of whom 37% responded.

Mr P Abel	Consultant Urologist, Hammersmith Hospital, London
Dr S Adam	Director of Health Services, Department of Health
Mr M Aitchison	Consultant Urologist, Gartnavel General Hospital, Glasgow
Professor Sir G Alberti	President, Royal College of Physicians
Professor F E Alexander	Professor of Epidemiology, University of Edinburgh
Mr J Anderson	Consultant Urological Surgeon, Royal Hallamshire Hospital, Sheffield
Mr R W Anderson	Economic Adviser, Department of Health
Dr I D Ansell	Consultant Histopathologist, Nottingham City Hospital
Mr I Appleyard	Consultant Urologist, Airedale General Hospital, Keighley
Professor P Armstrong	Professor of Radiology, St Bartholomew's Hospital, London
Dr D V Ash	Consultant in Clinical Oncology, Cookridge Hospital, Leeds
Professor Sir W Asscher	Chairman, United Kingdom Co-ordinating Committee on Cancer Research
Dr S Atkinson	Director of Public Health, Department of Health, London Regional Office
Mr M J Bailey	Consultant Urologist, St George's Hospital, London
Dr S I Baithun	Consultant Histopathologist, The Royal London Hospital
Dr M Baker	GP, Lincoln
Professor M R Baker	Cancer Lead, Yorkshire Cancer Network
Mr C J M Beacock	Consultant Urologist, Royal Shrewsbury Hospital

Mr R C Beard	Consultant Urologist, Worthing Hospital
Mr M Bellamy	Chief Executive, Ealing, Hammersmith and Hounslow Health Authority
Dr A Benghiat	Cancer Lead Clinician, Leicester Royal Infirmary
Mr M Bishop	Consultant Urologist, Nottingham City Hospital
Mr D T Blachford	Patient
Dr P Blain	Member of the National Cancer Implementation Group
Mr P Bollina	Consultant Urologist, Western General Hospital, Edinburgh
Dr D Bottomley	Consultant in Clinical Oncology, Cookridge Hospital, Leeds
Mr W G Bowsher	Consultant Urological Surgeon, Royal Gwent Hospital, Newport
Mr F J Bramble	Vice President, British Association of Urological Surgeons
Dr S A Bridgman	Consultant in Public Health Medicine, North Staffordshire Health Authority
Mr J P Britton	Consultant Urologist, St Richard's Hospital, Chichester
Ms J Brodie	Head of Cancer Support Service, CancerBACUP
Dr R Buchanan	Dean, Faculty of Clinical Oncology, Royal College of Radiologists
Mrs M Bullen	Director of Cancer Nursing, Maidstone Hospital, Kent
Ms K Burden	Research Nurse, Royal Berkshire Hospital, Reading
Dr H Burton	Consultant in Public Health Medicine, Cambridgeshire Health Authority
Mrs V Cameron	Secretary, Royal College of Psychiatrists
Mr D Campbell	Chief Executive, Liverpool Central Primary Care Trust
Professor L Cardozo	Professor of Urogynaecology, King's College Hospital, London
Dr B M Carey	Consultant Radiologist, Cookridge Hospital, Leeds
Mr M Carr	Patient
Ms L Cassapi	Conformal Therapy Research Radiographer, Clatterbridge Centre for Oncology
Mr D Chadwick	Consultant Urologist, South Cleveland Hospital, Middlesbrough
Mrs C Chard	Head of Hospital Business, ASTA Medica Ltd
Mr S Chiverton	Consultant Urologist, St Mary's Hospital, Portsmouth
Dr N Clarke	Head of Outcomes and Effectiveness, Department of Health

Mr N W Clarke	Consultant Urologist, Hope Hospital, Salford
Dr R Clements	Consultant Radiologist, Royal Gwent Hospital, Newport
Dr S Closs	Consultant in Palliative Medicine, Morriston Hospital, Swansea
Ms S Cochlin	Urology Nurse Specialist, Southport and Ormskirk District General Hospital
Dr C Coles	Specialist Registrar in Clinical Oncology, Addenbrooke's Hospital, Cambridge
Ms J Connelly	Director, Cancer Action Team, St Thomas' Hospital, London
Mr M J Coptcoat	Consultant Urologist, King's College Hospital, London
Dr G D Corcoran	Macmillan Consultant in Palliative Medicine, Walton Hospital, Liverpool
Professor J Corner	Director, Centre for Cancer and Palliative Care Studies, The Royal Marsden Hospital, London
Dr B Cottier	Head of Cancer Services Analysis, National Cancer Services Analysis Team
Mr A Cowles	General Secretary, Royal College of Radiologists
Dr I D Cox	GP, Pangbourne
Dr I G Cox	Macmillan GP Adviser in Cancer and Palliative Care, Birmingham
Mr D W Cranston	Consultant Urologist, Churchill Hospital, Oxford
Ms D Crowther	Chief Executive, Wirral Holistic Care Services
Dr M Cullen	Consultant in Medical Oncology, Queen Elizabeth Hospital, Birmingham
Mr J Cumming	Consultant Urologist, Southampton General Hospital
Mr G Das	Consultant Urologist, Mayday University Hospital, Surrey
Dr T W Davies	Director, East Anglian Cancer Registry, Cambridge
Ms J Dawson	Urology Nurse Specialist, Queen Elizabeth Hospital, Birmingham
Dr D Dearnaley	Consultant in Clinical Oncology, The Royal Marsden Hospital, Sutton
Mr A R De Bolla	Consultant Urological Surgeon, Wrexham Maelor Hospital
Dr G P Deutsch	Consultant in Clinical Oncology, Royal Sussex County Hospital, Brighton
Ms R Devlin	Practice Development Nurse, Derriford Hospital, Plymouth
Mr A Doble	Consultant Urologist, Addenbrooke's Hospital, Cambridge

Dr D Dodds	Consultant in Medical Oncology, Western Infirmary, Glasgow
Ms S Dolan	Critical Care Nurse Specialist, The Royal Marsden Hospital, Surrey
Professor L Donaldson	Chief Medical Officer, Department of Health
Dr R Donnelly	Medical Director, Janssen-Cilag Ltd
Dr C du Boulay	Director, Professional Standards Unit, Royal College of Pathologists
Mrs C Duddle	Macmillan Palliative Care Nurse Specialist, Fazakerley Hospital, Liverpool
Dr R Dunlop	Medical Director, St Christopher's Hospice, London
Ms J Eaton	Professional Affairs Officer, British Dietetic Association
Miss C Edwards	Assistant Director of Commissioning, North Derbyshire Health Authority
Dr J E Ellershaw	Medical Director, Liverpool Marie Curie Centre
Dr C Evans	Consultant Radiologist, University Hospital of Wales, Cardiff
Ms S Faithful	Lecturer in Cancer Care, Centre for Cancer and Palliative Care Studies, The Royal Marsden Hospital, London
Dr M Fallon	Consultant in Palliative Medicine, Western Infirmary, Glasgow
Ms J Farrell	Urology Nurse Specialist, Rotherham District General Hospital
Professor A Faulkner	Professor of Communication in Health Care, Great Barrow, Cheshire
Mr D P Fawcett	Consultant Urologist, Battle Hospital, Reading
Ms J Fenelon	Member of the National Cancer Implementation Group
Sir N Fenn	Chief Executive, Marie Curie Cancer Care
Professor I Finlay	Medical Director, Holme Tower Marie Curie Centre, Penarth
Dr C Fisher	Consultant Histopathologist, The Royal Marsden Hospital, London
Professor J Fitzpatrick	President, British Association of Urological Surgeons
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Appendix 3.4

Researchers carrying out literature reviews and complementary work

Overall co-ordinators

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i) Literature reviews

Professor M Mason Dr M Shelley Dr J Court and Miss K Burgon	Velindre NHS Trust, Cardiff

Contributed reviews which were used to inform guidance on all topics.

Professor I Higginson and Dr J Potter	Department of Palliative Care and Policy, King's College School of Medicine and Dentistry, London

Contributed reviews which were used to inform guidance on topics 3 and 4.

Mr A Flynn and Ms R Lewis	NHS Centre for Reviews and Dissemination, University of York

Contributed reviews which were used to inform guidance on topics 1 and 2.

Ms K Misso and Mrs B Coles	NHS Centre for Reviews and Dissemination, Velindre NHS Trust, undertook the literature searches for the review work.

ii) Patient views of urological cancer services

Ms R Miles and Ms C Smith	National Cancer Alliance, Oxford

iii) Economic reviews

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Appendix 3.5

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Appendix 4

Glossary of terms

Adjuvant treatment
Treatment given in addition to the main treatment, usually *radiotherapy* or *chemotherapy* given after surgery.

Aetiology
The origins or causes of disease.

Agonists
Drugs that trigger an action from a cell or another drug.

Alpha-fetoprotein (AFP)
A protein which may be found in the blood of men who have testicular cancer, used as a biochemical tumour marker.

Analgesia
Pain relief. In oral analgesia, drugs are given by mouth, whilst parenteral analgesia is given by injection. Titration of analgesia means gradually increasing the dose and/or using more powerful drugs until the pain is controlled.

Androgens
A family of hormones that promote the development and maintenance of male sex characteristics.

Antagonists
Drugs that oppose the action of another drug or natural body chemical.

Anti-androgens
Drugs that act by binding to the hormone receptors of cancer cells, thereby blocking the hormone from reaching, and stimulating, the cancer.

Aorta
The large artery originating from the left ventricle of the heart. Its branches carry blood to all parts of the body.

Assay
An analysis done to determine the presence of a substance and the amount of that substance.

Audit
A method by which those involved in providing services assess the quality of care. Results of a process or intervention are assessed, compared with a pre-existing standard, changed where necessary, and then reassessed.

Bacille Calmette-Guerin (BCG)
An anti-cancer drug that activates the immune system. Filling the bladder with a solution of BCG is a form of *biological therapy* for superficial bladder cancer. BCG is also the vaccine used to prevent tuberculosis.

Benign prostatic hyperplasia (BPH)
A non-cancerous condition in which an overgrowth of *prostate* tissue pushes against the *urethra* and the bladder, restricting or blocking the normal flow of urine. Also known as benign prostatic hypertrophy. This condition is increasingly common in older men.

Beta-human chorionic gonadotrophin (βhCG)
A hormone which may be found in the blood of men who have testicular cancer, used as a biochemical tumour marker.

Bilateral disease
Cancer that occurs in both paired organs, such as both kidneys or *testicles*.

Biological treatment
Treatment to stimulate or restore the ability of the immune system to fight infection and disease. Also used to lessen the side-effects that may be caused by some cancer treatments. Also known as *immunotherapy*.

Biopsy
Removal of a sample of tissue or cells from the body to assist in diagnosis of a disease.

Bisphosphonates
A type of cytotoxic drug used to treat bone metastases.

Bladder reconstruction
A surgical procedure to form a storage place for urine following a *cystectomy*. Usually, a piece of bowel is removed and is formed into a balloon-shaped sac, which is stitched to the *ureters* and the top of the *urethra*. This allows urine to be passed in the usual way.

Brachytherapy
Radiotherapy delivered within an organ such as the prostate.

Carcinoma in situ (CIS)
Cancer that involves only the cells in which it began and that has not spread to neighbouring tissues.

Case series studies
A series of case reports involving patients who were given similar treatment. Reports of case series usually contain information about individual patients including demographic information, information on diagnosis, treatment, response to treatment and follow-up.

Chemotherapy
The use of drugs that kill cancer cells, or prevent or slow their growth.

Cisplatin methotrexate vinblastine (CMV)
A type of *chemotherapy* using a combination of cisplatin methotrexate and vinblastine.

Clinical oncologist
A doctor who specialises in the treatment of cancer patients, particularly through the use of *radiotherapy*, but may also use *chemotherapy*.

Cognitive and behavioural interventions
Types of therapy, often delivered by psychologists, usually based on talking and practising specific types of voluntary activity. This group of interventions can include, for example, relaxation training, counselling, and psychological approaches to pain control.

Cohort studies
Research studies in which groups of patients with a particular condition or specific characteristic are compared with matched groups who do not have it.

Combination chemotherapy
The use of more than one drug to kill cancer cells.

Computed tomography (CT)
An x-ray imaging technique. In spiral CT the x-ray machine scans the body in a spiral path. Also known as helical CT.

Congenital abnormalities
Abnormalities that are present at birth.

Contralateral
Referring to the opposite side of the body.

Cryopreservation
Preservation by freezing.

Cystectomy
Surgery to remove all or part of the bladder.

Cystitis
Inflammation of the bladder.

Cystoscope
A thin, lighted instrument used to look inside the bladder and remove tissue samples or small tumours.

Cystoscopy
Examination of the bladder and *urethra* using a *cystoscope.*

Digital rectal examination (DRE)
An examination in which a doctor inserts a lubricated, gloved finger into the rectum to feel for abnormalities.

Epidemiology
The study of populations in order to determine the frequency and distribution of disease and measure risks.

Field
In *radiotherapy*, the area selected for treatment, on which the *radiotherapy* beam is focused.

Fraction
Radiotherapy is usually given over an extended period. The dose delivered each day is known as a fraction.

Genital
Referring to the external sex or reproductive organs

Germ cells
The reproductive cells of the body. In men, the testicular cell that divides to produce the immature sperm cells; in women the ovarian cell that divides to form the egg.

Germ cell tumours
Tumours that begin in the *germ cells*. 95% of all testicular cancers are germ cell tumours. Germ cell tumours in men are classified as either *seminomas* or *non-seminomas*.

Gleason scoring
A system of grading prostate cancer cells to determine the best treatment and to predict how well a person is likely to do. A low Gleason score means the cancer cells are very similar to normal prostate cells, a high Gleason score means the cancer cells are very different from normal.

Grade
The degree of malignancy of a tumour, usually judged by it histological features.

Great vessel involvement
Involvement of one of the five major blood vessels above the aortic arch.

Gynaecomastia
Enlargement of the breasts in men.

Haematuria
The presence of blood in the urine. Macroscopic haematuria is visible to the naked eye, whilst microscopic haematuria is only visible with the aid of a microscope.

Histology
Examination of the microscopic structure of tissue.

Hormone treatment
Treatment of cancer by removing, blocking or adding hormones.

Human papillomavirus (HPV)
A virus that causes warts and is often associated with some types of cancer.

Hypertension
Abnormally high blood pressure.

Immunotherapy
See *biological treatment.*

Impotence
Inability to have an erection adequate for sexual intercourse.

Incontinence
Inability to control the flow of urine from the bladder (urinary) or the escape of stool from the rectum (faecal).

Insulin-like growth factor (IGF)
Growth factors are chemicals that have a variety of roles in the stimulation of new cell growth and cell maintenance. IGF induces cell proliferation and is thought to be involved in the abnormal regulation of growth seen in cancer when produced in excessive amounts.

Intravenous urography
Radiological examination of the urinary tract, or any part of it, after the introduction of a contrast medium into a vein.

Intravesical treatment
Treatment within the bladder. Intravesical *chemotherapy* is given directly into the bladder through a catheter.

Lactate dehydrogenase (LDH)
An enzyme which may be found in the blood of men who have testicular cancer, used as a biochemical tumour marker.

Laparascopic surgery
Surgery performed using a laparascope; a special type of endoscope inserted through a small incision in the abdominal wall.

Libido
Sexual drive.

Luteinising hormone-releasing hormone (LHRH)
A hormone that controls the production of sex hormones in men and women.

LHRH analogues
Drugs that inhibit the secretion of *androgens* from the testes.

Lymph node dissection
See *lymphadenectomy.*

Lymph nodes
Small organs which act as filters in the lymphatic system. Lymph nodes close to the primary tumour are often the first sites to which cancer spreads.

Lymphadenectomy
A surgical procedure in which *lymph nodes* are removed and examined to see whether they contain cancer. Also known as lymph node dissection.

Lymphoedema
A condition in which excess fluid collects in tissues and causes swelling. It may occur in the legs after lymph vessels or *lymph nodes* in the groin are removed or treated with radiation.

Magnetic resonance imaging (MRI)
A non-invasive method of imaging which allows the form and metabolism of tissues and organs to be visualised (also known as nuclear magnetic resonance).

Maximum androgen blockade
The combined use of *LHRH analogues* and *anti-androgen* treatment.

Median
The middle value of an ordered set of measurements.

Mediastinum
The space in the chest between the lungs.

Medical oncologist
A doctor who specialises in the treatment of cancer by *chemotherapy*, and for some tumours *immunotherapy*.

Meta-analysis
A form of statistical analysis used to synthesise results from a collection of individual studies.

Metastases/metastatic disease
Spread of cancer away from the primary site.

Modal
The most commonly occurring value of a set of measurements.

Neo-adjuvant treatment
Treatment given before the main treatment; usually *chemotherapy* or *radiotherapy* given before surgery.

Nephrectomy
Surgery to remove all or part of a kidney. Radical nephrectomy removes the entire kidney, nearby lymph nodes and other surrounding tissue. Partial nephrectomy (also known as nephron-sparing surgery) removes only the tumour and part of the kidney surrounding it.

Nephron-sparing surgery
See *nephrectomy*.

Non-seminoma
A type of testicular cancer that begins in the *germ cells* (cells that give rise to sperm). Non-seminomas are identified by the type of cell in which they begin and include *teratomas*.

Oncologist
A doctor who specialises in treating cancer.

Oncology
The study of the biology and physical and chemical features of cancers. Also the study of the causes and treatment of cancers.

Orchidectomy
Surgery to remove one (unilateral) or both *testicles*.

Osteoporosis
Loss of bony tissue resulting in bones that are brittle and liable to fracture.

Palliative
Anything which serves to alleviate symptoms due to the underlying cancer but is not expected to cure it. Hence palliative care, palliative *chemotherapy*.

Para-aortic region
The prefix 'para' means besides. The region besides the *aorta*.

Pathologist
A person who specialises in the diagnosis of disease through study of the microscopic structure of cells and tissues.

Peri-operative
Around the time of surgery. Usually the time from admission to hospital to discharge following surgery.

Plaques
Patches of skin which appear different from the surrounding skin and are usually raised.

Proctitis
Inflammation of the rectum.

Prophylaxis
An intervention used to prevent an unwanted outcome.

Prostatectomy
Surgery to remove part, or all of the *prostate gland*. Radical prostatectomy is the removal of the entire *prostate gland* and some of the surrounding tissue.

Prostate gland
A small gland found only in men which surrounds part of the *urethra*. The prostate produces semen and a protein called *prostate specific antigen (PSA)* which turns the semen into liquid. The gland is surrounded by a sheet of muscle and a fibrous capsule. The growth of prostate cells and the way the prostate gland works is dependent on the male hormone *testosterone*.

Prostate specific antigen (PSA)
A protein produced by the *prostate gland* which turns semen into liquid. Men with prostate cancer tend to have higher levels of PSA in their blood (although up to 30% of men with prostate cancer have normal PSA levels). However, PSA levels may also be increased by conditions other than cancer and levels tend to increase naturally with age.

Prosthesis
An artificial device used to replace a missing part of the body.

Protocol
A policy or strategy which defines appropriate action.

Psychological interventions
Interventions directed at altering mental processes which do not involve the use of drugs or any physical or invasive procedure. These include a large group of therapeutic approaches including counselling, cognitive therapy, and relaxation.

Psychosexual
Concerned with psychological influence on sexual behaviour.

Psychosocial
Concerned with psychological influence on social behaviour.

Quality of life
The individual's overall appraisal of his/her situation and subjective sense of well-being.

Radical treatment
Treatment given with curative, rather than *palliative* intent.

Radioisotope treatment
A type of *radiotherapy*. A radioisotope liquid is given, either by mouth or as an injection into a vein. As the radioisotope material breaks down it releases radiation within the body.

Radiologist
A doctor who specialises in creating and interpreting pictures of areas inside the body. The pictures are produced with x-rays, sound waves, or other types of energy.

Radiotherapy
The use of radiation, usually x-rays or gamma rays, to kill tumour cells. Conventional external beam radiotherapy also affects some normal tissue outside the target area. Conformal radiotherapy aims to reduce the amount of normal tissue that is irradiated by shaping the x-ray beam more precisely. The beam can be altered by placing metal blocks in its path or by using a device called a multi-leaf collimator. This consists of a number of layers of metal sheets which are attached to the radiotherapy machine; each layer can be adjusted to alter the shape and intensity of the beam.

Randomised controlled trial (RCT)
A type of experiment which is used to compare the effectiveness of different treatments. The crucial feature of this form of trial is that patients are assigned at random to groups which receive the interventions being assessed or control treatments. RCTs offer the most reliable (i.e. least biased) form of evidence on effectiveness.

Refactory disease
Disease that is resistant to treatment.

Renal
Having to do with the kidneys.

Resection
The surgical removal of all or part of an organ.

Retroperitonium
The area behind the peritoneum (the tissue that lines the abdominal wall and covers most of the organs in the abdomen).

Salvage treatment
Treatment that is given after the cancer has not responded to other treatments.

Scrotum
The external sac that contains the testicles.

Seminoma
A type of testicular cancer.

Sperm banking
Freezing sperm in liquid nitrogen for use in the future. This procedure can allow men to father children after loss of fertility.

Staging
The allocation of categories (stage I to IV) to tumours defined by internationally agreed criteria. Stage I tumours are localised, whilst stage II to IV refer to increasing degrees of spread through the body from the primary site. Staging helps determine treatment and indicates prognosis.

Stoma
A surgically created opening.

Teratoma
A type of testicular cancer that arises from *germ cells* at a very early stage in their development.

Testicle or testis (plural testes)
Egg shaped glands found inside the scrotum which produce sperm and male hormones.

Testosterone
A hormone that promotes the development and maintenance of male sex characteristics.

Transitional cell carcinoma
A type of cancer which develops in the lining of the bladder, *ureters* or renal pelvis.

Trans-rectal ultrasound (TRUS)
An *ultrasound* examination of the prostate using a probe inserted into the rectum.

Trans-urethral resection (TUR)
Surgery performed with a special instrument inserted through the urethra.

Trans-urethral resection of the prostate (TURP)
Surgery to remove tissue from the prostate using an instrument inserted through the urethra. Used to remove part of the tumour which is blocking the urethra.

Tumour markers
Substances sometimes found in increased amounts in the blood, other body fluids or tissues which suggests that a certain type of cancer may be in the body, e.g. *PSA*.

Ultrasound
High-frequency sound waves used to create images of structures and organs within the body.

Ureters
Tubes which carry urine from the kidneys to the bladder.

Ureterscopic biopsy
A *biopsy* taken from the upper urological tract using a ureterscope; an endoscopic instrument passed through the *urethra* into the bladder and *ureters*.

Urethra
The tube leading from the bladder through which urine leaves the body.

Urinary diversion
Alternative methods of removing urine from the body following a *cystectomy*. Most commonly, a small piece of bowel is removed, the *ureters* are stitched to one end and the other end is attached to a *stoma* in the abdomen. Urine is brought to the surface and collected in a stoma bag. Alternatively, a pouch can be formed in the abdomen using a piece of bowel which is used to store urine. Urine is removed from the body by passing a small catheter through the stoma about four or five times per day to drain the urine (self-catheterisation).

Urogenital system
The organs concerned in the production and excretion of urine, together with the organs of reproduction.

Urologist
A doctor who specialises in diseases of the urinary organs in females and urinary and sex organs in males.

Urology
A branch of medicine concerned with the diagnosis and treatment of diseases of the urinary organs in females and the *urogenital system* in males.

Uro-oncologist
A doctor who specialises in the treatment of cancers of the urinary organs in females and urinary and sex organs in males.

Vasectomy
Surgery to cut or tie off the two tubes that carry sperm out of the *testicles*.

Vena cava
Either of two large veins that return blood to the heart. The superior vena cava returns blood from the head, neck and upper limbs and the inferior vena cava returns blood from the lower part of the body.

von Hippel-Lindau syndrome
A rare inherited disorder in which blood vessels grow abnormally in the eyes, brain, spinal cord or other parts of the body. People with von Hippel-Lindau syndrome have a higher risk of developing kidney and other types of cancer.

Watchful waiting
A surveillance technique. Treatment is omitted in favour of regular check-ups to see whether the cancer is beginning to grow.

Wilms' tumour
A kidney cancer that occurs in young children usually younger than five years old.

Coroners Service for Northern Ireland

JOHN L LECKEY LL.M.
SENIOR CORONER
FOR NORTHERN IRELAND

Dr Tony Stevens, Medica Director, BHSCT
Dr Charlie Martin, Medical Director, SEHSCT
Dr John Simpson, Medical Director, SHSCT
Dr Alan McKinney, Medical Director, WHSCT
Dr Calum MacLeod, Medical Director, NHSCT
Dr Carolyn Harper, Executive/Medical Director of Public Health
Ms Charlotte McArdle, Chief Nursing Officer

HSC Belfast Health and Social Care Trust
25 OCT 2013

Our ref: 1791-2011

21st October 2013

Dear Medical Director
and Chief Nursing Officer,

Re: Lynn Lewis, deceased

On 16th October 2013 I concluded an inquest into the death of a 38 year old woman, Mrs Lynn Lewis, who died in the Ulster Independent Clinic on 7th July 2011.

I believe sufficient background information is contained in the Verdict to which is annexed a copy of a statement on behalf of Professor Neil McClure the Surgeon, Dr Damien Hughes the Anaesthetist, the Ulster Independent Clinic and the nursing staff (copies enclosed). Also, I am enclosing a copy of a letter I have sent to the Minister for Health together with copies of the enclosures therein referred to.

At the conclusion of the inquest I stated that in addition to making a report pursuant to the provisions of Rule 23(2) of the 1963 Coroners Rules to the Minister, the Chief Medical Officer, the Regulation and Quality Improvement Authority and the Director of Public Health I would be writing to the Medical Director of all Northern Ireland Hospitals and the Northern Ireland Chief Nursing Officer. I would ask the Medical Directors to provide me with a collegiate response to the surgical and anaesthetic failings that the inquest has identified and I would ask for a similar response from the Northern Ireland Chief Nursing Officer in relation to nursing issues.

I should be grateful if you would acknowledge receipt of this letter and confirm that you will be responding in the manner I have requested. I, and no doubt the family also, require reassurance that all steps have been taken to ensure patient safety and

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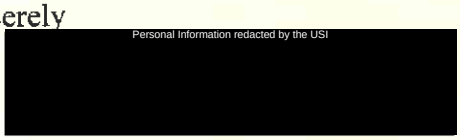
everything possible has been done or will be done to prevent the occurrence of a similar fatality or other serious adverse incident that has not resulted in a fatality.

I am sending a copy of this letter to the Minister, CMO, RQIA, Director of Public Health and the legal representatives.

I will look forward to hearing from you.

Yours sincerely



J L LECKEY
Senior Coroner for Northern Ireland

Encs

From the Deputy Chief Medical Officer
Dr Paddy Woods

HSS(MD)14 /2015

Department of
Health, Social Services and Public Safety
www.dhsspsni.gov.uk

Castle Buildings
Stormont
BELFAST
BT4 3SQ

Tel: Personal Information redacted by the USI
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For Action:

Chief Executives HSC Trusts
Chief Executive HSCB
Chief Executive PHA
Chief Executive RQIA *(for dissemination to independent sector organisations)*

Your Ref:
Our Ref: HSS(MD)14 /2015
Date: 18 August 2015

Dear Colleague

POLICY ON THE SURGICAL MANAGEMENT OF ENDOSCOPIC TISSUE RESECTION

ACTION REQUIRED

1. HSC Trusts and independent providers should process this regional policy template for endorsement by the organisational board, or equivalent;

2. HSC Trusts and independent providers should develop action plans to implement the various elements of the endorsed policy;

3. HSC Trusts should work with commissioners to address resource issues arising from these implementation plans in a phased, consistent and timely manner; and

4. the Public Health Agency should report on progress by 30 November 2015.

As a result of the verdict of the Coroner into the cause of death of Mrs Lynn Lewis in October 2013, work was commissioned on ensuring the safe and effective management of procedures involving the use of distending fluids in endoscopic procedures. In recognition of the limited guidance available on the management of these procedures, local work was commissioned, led by Dr Julian Johnston, Assistant Medical Director in Belfast Health and Social Care Trust.

The attached outline policy is the product of that work and we are now commending it for regional implementation.

The policy covers relevant issues including:

- appropriate preparation of patients prior to operation;
- selection of equipment and associated distending medium;
- precautionary measures associated with the distending medium selected;
- necessary measurements prior to, during and after these procedures;
- a good theatre environment in terms of team dynamics; and
- use of the WHO surgical checklist.

We believe this policy covers all aspects of concern raised by the Coroner in light of his findings in this tragic case.

We welcome your full assistance in this matter.

Yours sincerely

Personal information redacted by USI

Dr Paddy Woods
Deputy Chief Medical Officer

Personal information redacted by USI

Mrs Charlotte McArdle
Chief Nursing Officer

Cc HSC Trust Medical Directors
HSC Directors of Nursing Services
Chief Executive, BSO
Executive Medical Director/Director of Public Health PHA/HSCB
Dean Medical Faculty, QUB
Dean of Life and Health Sciences, UU
Chief Executive NIPEC
Chief Executive NIMDTA
Director of Safety Forum

This letter is available on the DHSSPS website at
www.dhsspsni.gov.uk/index/phealth/professional/cmo_communications.htm

Trust LOGO

Reference No:

Title:	Policy on the surgical management of endoscopic tissue resection, for example during urological, gynaecological and other relevant surgery.		
Author(s)	List name and titles of lead and additional author(s) or group responsible for drafting policy Include contact details		
Ownership:	Insert name of Director / service area / group / directorate		
Approval by:	Insert name of Trust committee / group responsible for approval	**Approval date:**	Insert date each committee approved
Operational Date:	December 2013	**Next Review:**	December 2014
Version No.	V0.2 **Supercedes**		
Key words:	Endoscopic, Resection, Prostatectomy, Myomectomy, TUR syndrome		
Links to other policies			

Date	Version	Author	Comments
20/11/2013	0.1	SE Trust	Initial Draft
03/12/2013	0.2	JR Johnston	Amalgamation of protocols from 5 Trusts.

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

Some endoscopic surgical procedures require the use of an irrigating fluid to dilate the operating field to enable a suitable field of vision and to wash away debris and blood. This includes operations such as,

- transcervical resection of the endometrium (TCRE),
- resection of prostate (TURP) and bladder tumours (TURBT),
- removal of uterine septations, polyps, endometrial ablations and also cystoscopy, arthroscopy, rectal tumour surgery, vesical ultrasonic lithotripsy and percutaneous nephrolithotripsy.

A serious complication of such irrigation is the systemic intravascular absorption of the irrigation fluid to the extent that serious overt symptoms are produced. This policy sets out the steps needed to reduce the risks of that happening. Using the national policies and guidelines identified in section 7 along with work already done within the province, its aim is to establish a regionally agreed set of precautions. Some of the recommendations can be instituted now and some will depend on longer term financing of equipment.

1.2 Irrigation fluids used

The irrigation fluid used for these electrosurgical procedures should,

- have neutral visual density so that the surgeon‘s view is not distorted.
- be nonconductive so the electrical current is not dissipated and can remain concentrated at the cutting point.
- be non-haemolytic so that haemolysis does not occur if it enters the circulation.

In the past, sterile water was used as the irrigant but was associated with significant morbidity because of water intoxication and intravascular haemolysis.

Modern non-electrolytic solutions containing glycine 1.5%, mannitol or sorbitol are optically clear and were introduced to prevent haemolysis, without dispersing the electric current used for cutting with the resectoscope. Their use in irrigation solutions has reduced the occurrence of significant haemolysis and death.

The most commonly used irrigation fluid is 1.5 % **glycine solution,** a non-essential amino acid with a low cost and lack of allergic reactions**.** However, it has an osmolality of 200 mOsm/L which is much lower than that of blood and large amounts of this hypotonic irrigation fluid, required to facilitate the procedure, may be absorbed systemically through a vascular bed. This may cause several serious complications known as the **TUR syndrome** which can occur in a variety of surgical disciplines.

Normal saline is used for irrigation with the bipolar resectoscope. Because of its greater plasma volume expansion, acute volume overload is more likely during absorption of normal saline compared with other irrigating solutions.

Moreover, it can cause hyperchloraemic acidosis due to its excessive content of chloride. Pulmonary oedema is a reported consequence.

1.3 TUR syndrome

This is manifested mainly through a classic triad of,

- fluid overload - acute changes in intravascular volume leading to circulatory overload, pulmonary oedema, cardiac failure and even cardiac arrest.
- dilutional hyponatraemia causing central nervous system (CNS) effects such as cerebral edema leading to agitation, confusion, convulsions and coma.
- direct toxicity and metabolism of glycine which may also cause CNS symptoms, most commonly transient blindness and CNS depression as it is an inhibitory neurotransmitter.

1.4 Purpose

This policy outlines a set of principles designed to reduce the development of the TUR syndrome.

1.5 Objectives

To reduce the likelihood of developing the TUR syndrome through,

- correct patient selection and preoperative preparation.
- selection of an appropriate surgical technique.
- the use of precautionary principles during the surgical procedure, including the correct procedure to follow in the safe management of irrigating fluid for urology and gynaecology.
- the application of monitoring aimed at detecting the early warning signs.
- establishing a theatre regime based on good theatre practice principles aimed at reducing the development of the TUR syndrome.

2.0 SCOPE OF THE POLICY

This policy applies to all staff who may be involved in the care of a patient in theatre who receives irrigating fluid into the bladder or uterus or any other organ where significant intravenous fluid absorption is a realistic possibility.

It applies to medical staff, nursing staff, midwives, operating department practitioners, technical staff, physicians' assistants (anaesthesia) and other theatre healthcare workers.

This policy does not cover the methods of treatment for the TUR syndrome.

3.0 ROLES/RESPONSIBILITIES

Medical staff - by careful consideration of the therapeutic choices when planning the service for endoscopic resection, can reduce the likelihood of the development of the TUR syndrome.

Management – by actively supporting the introduction of therapeutic modalities that aim to reduce the incidence of the TUR syndrome.

All staff involved in the care of the patient, especially in theatre, are responsible for implementing and adhering to the policy principles.

Each ward/theatre sister/charge nurse/clinician is responsible for ensuring staff comply with this policy and all relevant staff have the responsibility to ensure that they read and comply with the policy contents.

In the event of an untoward incident an IR1 form should be completed by either the medical officer or nurse in charge of the patient's care.

4.0 POLICY PRINCIPLES

4.1 Definitions

Osmolality: The concentration of osmotically active particles in a solution.

Hypertonic: Higher osmolality (concentration of particles) than what is found in normal cells.

Hyponatraemia: Lower sodium concentration than normally found in plasma.

Hypotonic (or hypo-osmolar): Lower osmolality (concentration of particles) than what is found in normal cells.

Resectoscope: An endoluminal surgical device comprising an endoscope (hysteroscope or cystoscope), sheaths for inflow and outflow, and an ''element'' that interfaces a specially designed electrode (or pair of electrodes) with a radiofrequency electrosurgical generator.

Policy Principles

4.2 Irrigating fluid is most frequently absorbed directly into the vascular system when a vein has been severed by electrosurgery. The driving force is the fluid pressure; the volume of fluid absorbed depending on the,

- duration of the procedure and resection time,
- degree of opening of blood vessels during surgery ,
    - vascularity of the diseased prostate, uterus, fibroid.
    - surgical disruption of the bladder, uterine vessels.
    - capsular or uterine wall perforation or apparent damage to a venous sinus.
- pressure of the distending fluid within the bladder or uterus,
    - height of the irrigation fluid bag above the patient (increased height implies increased hydrostatic pressure driving the fluid intravenously).
    - distension pressure applied to the irrigation fluid.

For safe endoscopic resection using irrigation fluid, the following topics should be covered within a set of policy principles,

1. Preoperative workup.
2. Selection of surgical technique.
3. Identification, control and management of haemorrhage.
4. Control of the absorption of irrigation fluid.

a. Dilutional Hyponatraemia.
b. Fluid overload.
c. Glycine toxicity.

5. Theatre environment.
   a. Decision making processes.
   b. Team dynamics.
   c. Lack of knowledge of the potential problems.

4.2.1 Preoperative workup

Some of these procedures are carried out on a predominantly elderly population with a higher incidence of coexisting disease. BPH affects 50% of males at 60 years and 90% of 85-year-olds and so TURP is most commonly performed on elderly patients, a population group with a high incidence of cardiac, respiratory and renal disease.

Careful preoperative workup of the patient should include, for example,

- a robust consent process leading to a truly informed patient aware of the hazards of endoscopic resection using irrigation fluids.
- a thorough physiological assessment with attention paid to risk factors such as hypertension, ischaemic heart disease, cardiac failure, anaemia.
- standard haematology and electrolyte analysis - to include a recent haemoglobin, serum sodium.
- careful consideration regarding blood grouping and cross-matching.
- recent investigations aimed at establishing the pathological anatomy and degree of surgical risk especially haemorrhage e.g. ultrasound scan.
- the ready availability of reports of such investigations.
- the timely commencement of any adjuvant therapy prior to the surgery e.g. before TCRE, especially if it helps to reduce the risk of haemorrhage and/or causes a reduction in tumour size.

4.2.2 Selection of surgical technique

All of the surgical teams (urology, gynaecology) in NI, practicing this type of surgery, should become fully cognoscente of the risks of the TUR syndrome and work together to develop a co-ordinated regional approach where they take steps to,

- agree a programme of change for the cessation of glycine use.
- develop or adopt surgical techniques that do not rely on glycine as an irrigant.
- use instruments and equipment that help to control or reduce vesical or uterine pressure.
- establish a set of safe practice standards.

Urology

Absorption in excess of 1 litre of glycine solution, which is associated with a statistically increased risk of symptoms, has been reported in 5–20% of the TURPs performed. Extravasation is the cause in ~20% of these patients.

While electrolyte-containing solutions such as normal saline (NS) are not suitable for RF surgery with monopolar RF systems, the development of

bipolar radiofrequency (RF) instrumentation for endoscopic resection procedures has allowed the application of NS as a distending medium.

Therefore, the adoption of bipolar TURP or laser prostatectomy allows NS irrigation in urology and permits the removal of glycine and its inherent risks from theatre. The risks of the hyponatraemic and hypo-osmolar aspects of the TUR syndrome are eliminated.

However, it should be remembered that the use of NS is not without risk because there will still be fluid absorption with plasma volume expansion. Some consider acute volume overload is more likely during absorption of normal saline compared with other irrigating solutions.

As long as they are proven to be safe and effective as judged by the NICE interventional procedure programme, bipolar RF systems and other technique e.g. laser systems, should be introduced regionally and the use of glycine as a irrigant terminated.

Gynaecology

Fluid absorption is slightly more common during TCRE than during TURP. The first generation endometrial ablative techniques including TCRE and rollerball endometrial ablation (REA) are all endoscopic procedures. Their effectiveness (in comparison with hysterectomy - the existing gold standard) has been demonstrated in a number of randomised controlled trials. Although less morbid than hysterectomy, they are associated with a number of complications including uterine perforation, cervical laceration, false passage creation, haemorrhage, sepsis and bowel injury and, importantly, the fluid overload and hyponatraemia associated with the use of 1.5% glycine irrigation fluid resulting in the serious and occasionally fatal consequences discussed above.

There are now second generation ablative techniques which do not require the use of electrocautery or the use of glycine or other distension fluids. They avoid the serious risk of hyponatraemia and represent simpler, quicker and potentially more efficient means of treating menorrhagia. Examples of second generation ablative techniques are fluid filled thermal balloon endometrial ablation (TBEA), radiofrequency (thermoregulated) balloon endometrial ablation, hydrothermal endometrial ablation, 3D bipolar radiofrequency endometrial ablation, microwave endometrial ablation (MEA), diode laser hyperthermy, cryoablation and photodynamic therapy.

As long as they are proven to be safe and effective as judged by the NICE interventional procedure programme, the use of second generation ablative techniques and bipolar RF systems should be introduced regionally and the use of glycine as a irrigant terminated.

4.2.3 Identification, control and management of haemorrhage.

Blood loss can be difficult to quantify and may be significant. Close attention to the patient's clinical state and good communication between surgeon, anaesthetist and the theatre team is vital.

Because of generalised physiological effects of haemorrhage and the increased likelihood of fluid absorption when using irrigation fluid, the presence of significant bleeding should act as a trigger for,

- increased vigilance for development of fluid overload, hyponatraemia.
- additional help from medical and nursing staff to assist by scrubbing in.
- increased frequency of haemoglobin and/or haematocrit measurements.
- preparation of blood for cross matching.
- cessation of the operation once bleeding is controlled.

4.2.4 Control of the absorption of irrigation fluid

The choice of surgical technique and equipment may reduce the complications from irrigation fluid especially if glycine use stops but continued attention to controlling fluid absorption will still be needed with normal saline.

Until glycine use stops, symptoms related to fluid absorption will develop in 3 – 5% of patients with neurological symptoms being prominent. To control the effects of fluid absorption, the theatre team should pay particular attention to

a) hyponatraemia
b) fluid volumes.

a. Dilutional Hyponatraemia

The uptake of 1000 ml of fluid corresponds to an acute decrease in the serum sodium concentration of 5-8 $mmol.l^{-1}$. Encephalopathy, seizures and even cerebral oedema may develop when the sodium concentration falls below 120mmol/l. However, even markedly hyponatraemia patients may show no signs of water intoxication. The crucial physiological derangement of CNS function is not just hyponatraemia *per se*, but also the presence of acute hypo-osmolality.

Also, a patient's serum sodium concentration and osmolality may continue to decrease for some time after the procedure because irrigant can be slowly absorbed from the perivesicular and retroperitoneal spaces. Therefore, the TUR syndrome can start 4 to 24 hours later – intraoperatively, in the recovery ward or back in the ward.

Whereas hyponatraemia occurs with equal frequency in men and women, premenopausal women are 25 times more likely to die or have permanent brain damage than men or postmenopausal women, most likely an oestrogen effect. This effect is compounded because fluid absorption is slightly more common during TCRE than during TURP.

Serum Sodium measurement

Monitoring serum sodium concentration during TURP is common practice and a low value will confirm the diagnosis of hyponatraemia and is effective for assessing intravascular absorption. Significant decreases from a normal preoperative level can occur after just 15 minutes of starting resection. Levels below 120 mmol/L are invariably symptomatic and a rapid fall is more likely to produce symptoms.

Point-of-care testing (POCT) is defined as medical testing at or near the site of patient care. It brings the test conveniently and immediately to the patient. This increases the likelihood that the patient, physician, and care team will receive the results quicker, which allows for immediate clinical management decisions to be made. They can be used to measure haematocrit, determine haemoglobin and measure serum electrolytes.

Using POCT apparatus for the measuring and having a result in minutes is a significant aid in diagnosing hyponatraemia as early as possible. Such POCT equipment must/should be available when these techniques for tissue resection are used.

It is often only measured at the end of surgery but this monitoring technique is best applied before and repeatedly during surgery so that it can act as a warning system for hyponatraemia. Any patient receiving glycine in theatre must have a measurement(s) made,

- as a preoperative baseline prior to the start of surgery.
- intermittently throughout a case as a routine.
- if there is a 1000mls deficit.
- if the surgery is longer than 30 minutes.

Staff must be readily available who are trained to use this POCT equipment.

b. Fluid volumes

Estimates of amount of fluid absorbed range from 10 – 30 mls per minute of resection time; over a 45 – 60 minute case that could equate to 1 – 1.8 litres. The best management of fluid overload is to prevent its occurrence by constantly and accurately monitoring the distending fluid input and output. The surgeon should be notified about ongoing fluid absorption early enough for steps to be taken to prevent excessive absorption.

Volumetric fluid balance is based on the calculation of the difference between the amount of irrigating fluid used and the volume recovered. Positive values are regarded as absorption.

However, calculation of systemic absorption is complicated by 4 factors:

1. It may be difficult to collect all of the media (fluid, urine and blood) that passes out of the operative area, including that which falls on the procedure or operating room floor.
2. the actual volume of media solution in 3L bags is typically more than the labelled volume.
3. difficulties in estimating the volume of media left in a used or ‘emptied’ infusion bag.
4. systemic absorption that in some instances may occur extremely rapidly.

While these factors can make volumetric fluid balance measurement an unreliable tool, it is considered a minimum necessity that the theatre team measure fluid input and overt output during such surgery and calculate a running deficit.

Bearing these difficulties in mind, a member of staff must be assigned to this duty before the start of every case. They will need to be proficient and practiced in this technique and must take responsibility for measuring the input and output, calculating the deficit and recording these details. They should remain in theatre for the duration of the procedure, in the same fashion as the surgeon.

The simplest method of monitoring comprises manually subtracting the volume collected from the volume infused, considering all sources including the resectoscope outflow; the ‘‘perineal’’ collection drape, which includes a pouch to capture spilled fluid and special apparatus to collect fluid spilled on the floor. Specialist draping systems are readily available for such fluid collection and should be used. Even so, accurate measurement can be difficult.

Each patient who has any irrigating fluid erected must have a fluid management chart (appendix X) commenced. Measuring the input and outputs and calculating the deficit should be done as a minimum every time a bag (often 3 litre) is hung up and the details clearly expressed verbally to the surgeon and all other theatre staff. These details should also be recorded on the dedicated fluid management chart. They might also be displayed on a white marker board in the theatre.

A second bag should not be commenced until a deficit amount has been calculated and it is agreed to be safe to proceed. It should be unusual to need a third bag but if it is, it should be done under the same circumstances. (??) At the end of the procedure, the final calculations must be made; the inputs, outputs and deficit. These should be expressed clearly to the surgeon and anaesthetist and recorded on the chart.

The fluid management chart must follow the patient into the recovery ward. All fluid balances must be handed over to recovery ward staff as part of the normal nursing and medical handover. The chart is then to be filed in the clinical record.

The limitations of such manual measurement may make it preferable to use an automated fluid measurement system that takes into account an exact measurement of infused volume as well as all of the potential sources of returned media. Such systems provide continuous measurement of the amount of distending media absorbed into the systemic circulation by using the weight of the infused volume. Such systems need evaluated in NI.

Maximum fluid deficit
Prevention of the TUR syndrome requires that the team have a protocol for responding to any escalating fluid absorption and there must be agreed volume thresholds for action. These thresholds may necessarily vary somewhat, depending on a number of factors that include the nature of the surgery, the nature of the media (isotonic or hypotonic) and the patient’s baseline and intraoperative medical condition e.g. presence of haemorrhage.

It has been shown with routine postoperative CT imaging of the brain that cerebral oedema can occur with as little as 500 mL of hypotonic solutions. The surgeon and anaesthetist must be informed by the nurse when there is a 500mls deficit. The nurse must ensure that the surgeon and anaesthetist acknowledge that they have received this information. This must be documented in the notes along with any action taken.

A 500 ml threshold may be appropriate for those who are older and/or medically compromised, but for healthy individuals, absorption of up to 1000 mL can generally be tolerated. The surgeon and anaesthetist must be informed by the nurse when there a 1000mls deficit. The nurse must ensure that the surgeon and anaesthetise acknowledge that they have received this information. This must be documented in the notes along with any action taken.

For elderly (? define) patients and others with comorbid conditions including compromised cardiovascular systems, a maximum fluid deficit of 500 mL is recommended. Surgery must stop unless haemorrhage needs controlled.

For healthy patients, the maximum fluid deficit of 1000 mL is suggested when using hypotonic solutions (glycine). Surgery must stop unless haemorrhage needs controlled.

The maximum limit for isotonic solution (normal saline) is unclear, but 2500 mL has been advocated. Surgery must stop unless haemorrhage needs controlled.

Further preventative measures

There are several precautions that reduce the risk of fluid absorption and its associated dangers. These are especially important because calculating the fluid absorption can be difficult.

These include limiting the,

1. Distension pressure by,
   - keeping the uterine cavity distention pressure at the lowest pressure necessary to distend the uterine cavity consistent with good visualisation and ideally should be maintained below the mean arterial pressure (MAP).

     It is estimated that approximately 40mmHg distending pressure is required to obtain clear vision. At pressures between 40mmHg and approximately 100mmHg (MAP), blood will continue to escape from disrupted capillaries until it is stopped by the tamponade. At this point, when continuous flow is used through the resectoscope, the blood within the cavity will be removed and a clear field of vision will be maintained. Dropping the pressure permits further bleeding. If the pressure is raised above the MAP, the pressure not only prevents the flow of blood out of disrupted vessels but actually forces the distension fluid medium in the reverse direction into the vessels.
   - attempting to limit the height of the irrigating solution container to 60 cm (figure to be agreed) above the patient and certainly never above 100cm.

Theatre teams must have a procedure for checking and maintaining an agreed height.
- not applying pressure bags to the irrigation fluid bag.
- insufflating irrigation fluid by using a pressure controlled pump device.

2. Operation time - restricting resection time to 60 minutes. Theatre teams must have an establish mechanism for measuring time and procedures for alerting surgeon and anaesthetist.

4.2.5 Theatre environment

A good theatre environment in terms of team dynamics is essential for the safe performance of these surgical procedures. There must be careful monitoring of fluid balance along with the clear communication of that balance to the surgical and anaesthetic members of the team.

- Theatre staff must always be aware of the potential hazards of, and equipment used, for any surgical procedure before it is performed.
- One member of the theatre team must be assigned to the duty of collecting, calculating and recording the irrigation volumes in/out and deficits. They will need to be proficient and practiced in this technique. It would not be expected that the surgeon should have to operate and also supervise this function at the same time. They should remain in theatre for the duration of the procedure, in the same fashion as the surgeon.
- Medical staff must always have situational knowledge of the theatre environment that they are working in and the availability (or non-availability) of any theatre equipment they consider necessary. They must be informed, in good time, of any equipment that is not working.
- Nursing staff should have a working knowledge of any equipment being used in their theatre or have the immediate presence of technical staff who do have that knowledge.

WHO checklist

Completion of the WHO surgical checklist with the sign in, time out and sign out must be adhered to. This will allow a surgical, anaesthetic and theatre team brief at the beginning for the whole theatre team and an opportunity to check that everything is in place to perform the biochemical and volumetric monitoring.

It will also ensure at the sign out that any problems e.g. over a fluid deficit, are identified early. On a regional basis, adoption of a modified WHO checklist for this kind of procedure should be investigated and piloted.

5.0 IMPLEMENTATION OF POLICY

This policy, after it is agreed, is to be implemented throughout NI in each of the 5 Trusts.

5.1 Resources

There will be resource implications in terms providing surgical equipment that can be used without needing glycine as an irrigant, POCT monitoring equipment for theatres and training for staff.

6.0 MONITORING

TBC

7.0 EVIDENCE BASE / REFERENCES

1. R. G. Hahn. Fluid absorption in endoscopic surgery. Br J Anaesth 2006; 96: 8–20.
2. Practice Committee of the AAGL Advancing Minimally Invasive Gynaecology Worldwide . Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media. Journal of Minimally Invasive Gynaecology (2013) 20, 137–148.
3. Dietrich Gravenstein. Transurethral Resection of the Prostate (TURP) Syndrome: A Review of the Pathophysiology and Management. Anesthesia & Analgesia. 1997; 84: 438-46
4. Varol N, Maher P et al. A literature review and upodate on the prevention and management of fluid overload in endometrial and hysteroscopic surgery. Gynaecological Endoscopy 2002; 11: 19-26
5. Blandy JP, Notley RG, Reynard JM. Transurethral Resection. Pub, Taylor and Francis 2005. http://www.baus.org.uk/Resources/BAUS/Transurethral%20Resection.pdf
6. Marszalek M, Ponholzer A et al. Transurethral Resection of the Prostate. European urology supplements 8 (2009) 504–512.
7. Indman PD, Brooks PG et al. Complications of fluid overload from Resectoscopic surgery. J Amer Assoc of Gynaecolig laparoscopists 1998; 5: 63-67.
8. Hawary A, Mukhtar K et al.Transurethral Resection of the Prostate Syndrome: Almost Gone but Not Forgotten. Journal of Endourology 2009; 23: 2013-20.

8.0 CONSULTATION PROCESS

Insert a list of those groupings consulted in the development of this policy e.g. Trade Unions, Specialist Committees, User groups, Section 75 groups.

9.0 APPENDICES / ATTACHMENTS

Appendix 1 = draft Theatre record form
Appendix 2 = Theatre based Summary form.
Appendix = Evidence based recommendations from AAGL Practice Committee.

10.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out.
The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact. ☐

SIGNATORIES

_____ **Date:** _____
Author

_____ **Date:** _____
Director

Trust LOGO

Peri-operative fluid recording chart

Consultant: _____ Date: _____ Ward: _____ Operation: _____	Addressograph Label

Irrigation fluid Start time: _____= 0 mins___ Type of fluid used _____

Serum Sodium: = _____ mmol/L Haemoglobin: _____g/dL.

Time (mins)	Irrigation In (mls)	Running total In	Irrigation Out (mls)	Deficit (mls)	Running deficit Out	Serum Sodium	Sign
5						Mmol/L	
10						Mmol/L	
15						Mmol/L	
20						Mmol/L	
25						Mmol/L	
30						Mmol/L	
35						Mmol/L	
40						Mmol/L	
45						Mmol/L	
50						Mmol/L	
55						Mmol/L	
60						Mmol/L	
						Mmol/L	

Total fluid In	=	Surgeon Signature	
Total Fluid Out	=	Anaesthetist Signature	
Deficit	=	Nurse Signature	

Trust LOGO

Continued.

Time (mins)	Irrigation In (mls)	Running total In	Irrigation Out (mls)	Deficit (mls)	Running deficit Out	Serum Sodium	Sign
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	
						Mmol/L	

Irrigation In = after each fluid bag (mls)	Irrigation Out = record - suction canister volumes (mls) - fluid in drapes - fluid from floor suction
Record amount 'in' each time use Ellick evacuator	Record amount 'out' each time use Ellick evacuator

Maximum deficit: Inform surgeon before reach

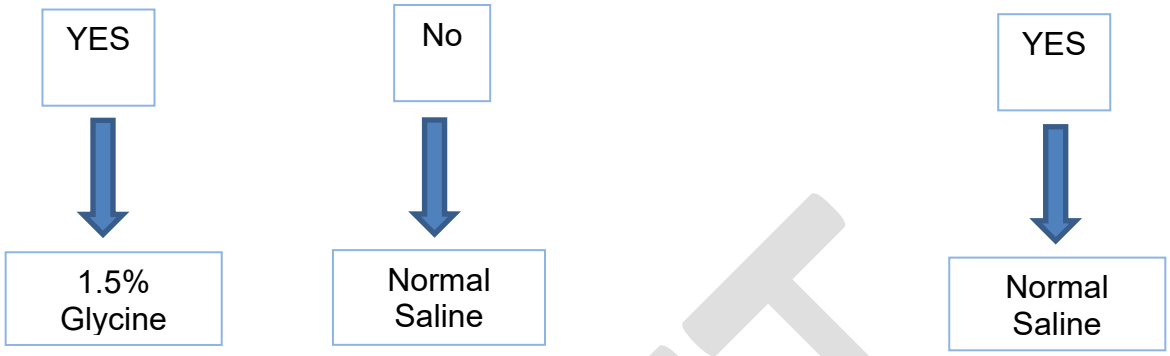
1.5% Glycine	500 mls – Elderly, comorbidities. 1000 mls – healthy
Normal Saline	1000 mls

Appendix 2

Managing Fluid Media: 3 steps in Theatre

1. Choose Right Fluid

Monopolar diathermy **Bipolar diathermy**



2. Minimise Absorption during surgery
   - When the Fluid bag is 100 cm above the level of the uterus, gravity creates pressure. This is approximately 60-100 mmHg and adequate for most cases.
   - A pressure cuff does not allow precise control of the pressure
   - For cases other than diagnostic hysteroscopy, a fluid management system should be used if available. If not, the lowest pressure possible should be used.

3. Recognise Early if excess absorption has occurred

   Requires accurate measurement of fluid going into the uterus and all fluid coming out, either through the outflow sheath or via the vagina into the collection receptacle.

   A team member should not have other duties to perform while monitoring fluid balance. This should use the attached sheet for intraoperative documentation.

   The operating surgeon should include the fluid deficit in the *Operative Findings* when writing the operative notes

   Complex cases such as intramural fibroids should have preoperative measurement of serum electrolytes. Team brief should include discussion of limiting iv fluids intraoperatively.

   When Glycine is used the procedure should stop when 500ml deficit is reached

   When Normal Saline is used the procedure should stop when 2500mls deficit is reached. In patients with heart failure this threshold should be reduced according to severity of their condition.

Appendix 3

Recommendations

Evidence Level A

1. Intracervical injection of 8 mL of a dilute vasopressin solution (0.05 U/mL) immediately prior to the procedure reduces distending media absorption during resectoscopic surgery. Such administration may also reduce the force required for cervical dilation
2. The uterine cavity distention pressure should be the lowest pressure necessary to distend the uterine cavity and ideally should be maintained below the mean arterial pressure (MAP).

Evidence Level B

3. Excessive absorption of hypotonic fluids such as glycine 1.5% or sorbitol 3% can result in fluid overload and hypotonic hyponatraemia, causing permanent neurologic complications or death.
4. The risk of hypotonic encephalopathy is greater in reproductive-aged women than in postmenopausal women.
5. When compared with electrolyte-free media, saline appears to have a safer profile.
6. Excessive absorption of isotonic fluids such as normal saline can cause severe complications. Although isotonic fluids do not cause cerebral oedema, there is still a mandate for continuous and accurate measurement of input and output for the calculation of fluid absorption.
7. The risk of systemic absorption varies with the procedure and increases when myometrial integrity is breached with procedures such as myomectomy. In such instances, patients should be counselled that more than one procedure may be required.
8. Due to the conflicting evidence regarding their impact on the volume of fluid deficit during resectoscopic surgery, the decision to use a gonadotropin-releasing hormone (GnRH) agonist in premenopausal patients to reduce extent of fluid deficit should be made at the discretion of the provider.

Evidence Level C

9. CO_2 is a suitable medium for the performance of diagnostic hysteroscopy but should not be used for operative hysteroscopy because of its impact on Hysteroscopic visualization and the risk of CO_2 embolus.
10. Before performing operative hysteroscopy with liquid distending medium, it is important to purge the air out of the system and during the procedure to change the liquid-containing bag before it is completely emptied.
11. The risks associated with distending media overload may be reduced by limiting the degree of preoperative hydration with oral or intravenous fluids.
12. Shortly prior to performing resectoscopic surgery, it is advisable to obtain baseline levels of serum electrolytes including sodium, chloride, and potassium in women on diuretics or with medical conditions that may predispose to electrolyte disorders.
13. The following statements on maximum fluid deficits are based on expert opinion. The patient should be carefully evaluated, with consideration to terminating the procedure expeditiously if intravasation is known or thought to reach the volume in these clinical contexts. For elderly patients and others with comorbid conditions including compromised cardiovascular systems, a maximum fluid deficit of 750 mL is recommended.

a. For healthy patients, the maximum fluid deficit of 1000 mL is suggested when using hypotonic solutions. This is based on a decrease in serum sodium of 10 mmol, with absorbed volume of around 1000 mL. The maximum limit for isotonic solution is unclear, but 2500 mL has been advocated in the previous AAGL Guidelines. Individualization and the anesthesiologist's opinion should be obtained.
b. When high-viscosity distending media are used, the maximum infused volume should not exceed 500 mL, and in the elderly and those with cardiopulmonary compromise should not exceed 300 mL.

14. When maximum absorption occurs with electrolyte-free distending media, immediate measurement of plasma electrolytes and osmolality is recommended.
15. Normal saline should be used wherever possible for operative hysteroscopic surgery to reduce the risk of hyponatremia and hypo-osmolarity. Normal saline should be used for distention during operative hysteroscopic procedures not requiring the use of monopolar electrosurgical instruments.
16. The surgical team should be prepared to accurately monitor distending fluid medium input and output, including all 3 potential sources: return from the hysteroscope, spill from the vagina, and loss to the floor. An automated system for continuous calculation of fluid deficit is recommended.
17. The use of an automated fluid management system is recommended. Such systems should ideally comprise an infusion pump that allows determination and continuous monitoring of true intrauterine distention pressure and a system for accurate measurement of fluid deficit.
18. The surgical team should, prior to the start of the case, predetermine the maximum acceptable volume of systemically absorbed distending media considering both the medical condition of the patient, and the osmolality and electrolyte content of the media to be used

From:
Practice Committee of the AAGL Advancing Minimally Invasive Gynaecology Worldwide . Practice Report: Practice Guidelines for the Management of Hysteroscopic Distending Media. Journal of Minimally Invasive Gynaecology (2013) 20, 137–148.

Subject: 20100921 Email from Diane Corrigan to Brian Armstrong BHSCT re Radical Pelvic Surgery Patients

---

From: Corrigan, Diane <[redacted]>
Sent: Tuesday, September 21, 2010 7:43:03 PM
To: Armstrong, Brian <[redacted]
Gillian Rankin
Cc: Stephen Hall
Beth Malloy [redacted]>; Welsh, Jennifer
[redacted]; Donnelly, Patricia <[redacted]
Hagan, Chris [redacted]; McCann, Bronagh
[redacted]>; McClenaghan, Karen
[redacted]; Seamus McGoran
[redacted]; Williamson, Sarah <[redacted]
McNicholl, Catherine [redacted]; Thompson, Jennifer
[redacted]
Subject: Re: Radical Pelvic Surgery Patients

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Brian
Thank you very much for accommodating these patients. I am sure the HSCB colleagues in the Armagh office will be prepared to discuss contract issues with you. However last time I checked the BHSCT performance against SBA volumes for the south LCG seemed to be substantially below contract. In contrast it is way over for patients from the north LCG, so from your point of view the work may be exceeding your capacity - but that is not the fault of too little income from the southern office.

I think some further discussion is needed on which patients should be transferred out. Possibly north LCG residents living close to the catchment boundary with CAH?

Regards
Diane

----- Original Message -----
From: Armstrong, Brian <[redacted]>
To: Rankin, Gillian <[redacted]>
Cc: Corrigan, Diane <[redacted]; Hall, Stephen
[redacted]>; Beth Malloy [redacted]>; Welsh, Jennifer
[redacted]; Donnelly, Patricia
[redacted]
Hagan, Chris <[redacted]>; McCann, Bronagh
[redacted]>; McClenaghan, Karen
[redacted]>; [redacted]
Seamus McGoran [redacted] Williamson, Sarah
[redacted]
McNicholl, Catherine [redacted]

<[redacted]>
Sent: Tue Sep 21 18:05:11 2010
Subject: Radical Pelvic Surgery Patients

Dear Gillian,

Further to the recent request from the SHSCT to BHSCT re the treatment of 5 radical pelvic surgery patients, I would like to confirm the BHSCT have managed to identify capacity to treat these patients in October. The Belfast Trust (as part of Team East) is working with PMSID to implement the recommendations within the Regional Review, however these have not been funded recurrently to date. Therefore, in this instance, given the significant impact this displaced activity will have on the service in Belfast in October, I would request the SHSCT could work with us to identify the equivalent capacity within their Trust to treat the displaced BHSCT demand. This is equivalent to 5 inpatient lists.

It would be helpful going forward if the SHSCT patients are taken via the Regional MDM route. I understand there have been delays in realising this due to lack of Oncology support. However, as an interim measure it would be useful if a surgeon could telelink into the MDM to handover the cases. Regardless of what interim arrangements are put in place however, in the short term it is imperative that appropriate referrals are sent to the specialist surgical team in BHSCT in a timely fashion to ensure appropriate management of these patients.

Kind regards

Brian

Co-Director

Acute Services

Mobile

[redacted]

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Subject: 20100921 Emails between SHSCT and BHSCT re patients requiring treatment

---

-----Original Message-----
From: Williamson, Sarah
Sent: 21 September 2010 17:45
To: Porter, Alison <Personal Information redacted by the USI>; martina.corrigan Personal Information redacted by the USI
Cc: McCann, Bronagh Personal Information redacted by the USI >; McClenaghan, Karen Personal Information redacted by the USI ; Hagan, Chris Personal Information redacted by the USI >
Subject: FW: prostate surgery

Alison/Martina

See below. The Co-Director for Urology will be emailing Dr. Rankin to notify her of this formally.

As discussed, we will be in touch by tomorrow early afternoon (at the latest) with Outpatient Appointment times for these patients at Monday's clinic.

Kind regards,

Sarah

-----Original Message-----
From: McCann, Bronagh
Sent: 21 September 2010 17:33
To: Williamson, Sarah
Cc: McClenaghan, Karen; Hagan, Chris; Rajan, Nambi; Keane, Patrick; Armstrong, Brian
Subject: RE: prostate surgery

Hi Sarah

Further to our discussion I want to confirm that we can accept the 5 patients referred for surgery to Belfast in October, as per the recommendations set out in the Regional Review. These patients will require 5 inpatient surgical lists for treatment. Given the fact that there is currently no allocation of recurrent funding from the Regional Review at this stage, I feel it's appropriate to request the SHSCT accommodate the equivalent activity in displaced lists. Brian will write to the SHSCT and commissioners separately to raise this issue.

I am aware that there are a number of details to be organised asap for these patients and Kate will liaise with your team directly to confirm.

Thanks
Bronagh

-----Original Message-----
From: Williamson, Sarah
Sent: 21 September 2010 12:40
To: Hagan, Chris; McCann, Bronagh
Cc: McClenaghan, Karen

Subject: FW: prostate surgery
Importance: High

See below- more patients requiring treatment in Belfast in the next week or two. As per PMSID guidance, we need to respond today with intention to treat, likely timeframe and either cost/displaced activity which could be sent to CAH at equitable activity level....

So far there are four, with a potential fifth:

Personal Information redacted by the USI - radical cystoprostatectomy and illeal conduit urinary diversion (has a date 27/09/10 in CAH) Personal Information redacted by the USI - nephrectomy, radical cystectomy and urinary diversion (potential date 20th Oct in CAH) Personal Information redacted by the - RRP (booked 24/09/10 CAH) Personal Information redacted by the USI - RRP (booked 1/10/10 CAH)

Personal Information redacted by the USI - ?Cystectomy (scheduled 13/10/10)

Thanks!

Sarah

-----Original Message-----
From: Porter, Alison Personal Information redacted by the USI
Sent: 21 September 2010 08:29
To: Williamson, Sarah
Cc: Corrigan, Martina2; Graham, Vicki
Subject: prostate surgery
Importance: High

Hi Sarah

Apologies

We have been trying to do a lot of work with urology and have two more surgeries planned

2 radical prostatectomies - One is booked for this Friday - Personal Information redacted by the USI and ? Personal Information redacted by the USI next Friday. - It would probably be sensible that we proceed with these, but can you discuss with your team.

Personal Information redacted by the USI (one of the patients we discussed yesterday has been scheduled for 20th Oct, although the patient does not know yet. (may help your discussion re dates in Belfast)

We also have a patient Personal Information redacted by the USI referred for oncology opinion first to Dr McAleese, hopefully she will be seen this week, although it is already overbooked - Personal Informa is then for possible cystectomy on 13th October - again the patient has not been informed of this date.

Can you please advise what your Trust's views are on these patients? I will be in a meeting with Dr Rankin until about 10.30, but can check the blackberry if you have nay updates before you go to the ITT meeting

Thanks

Alison

Alison Porter

Head of Cancer Services

Mandeville Unit

Craigavon Hospital

68 Lurgan Road

Portadown

BT63 5QQ

Tel Personal Information redacted by the USI

Mobile : Personal Information redacted by the USI

Subject: 20100922 Email from Chris Hagan to Diane Corrigan raising concern about delayed referral to commissioner in 2010

From: Corrigan, Diane <Personal Information redacted by the USI
Sent: Wednesday, September 22, 2010 10:04:34 AM
To: Hagan, Chris <Personal Information redacted by the USI>; Armstrong, Brian <Personal Information redacted by the USI> Personal Information redacted by the USI <Gillian Rankin t>
Cc: Stephen Hall Beth Malloy >; Welsh, Jennifer <Personal Information redacted by the USI>; Donnelly, Patricia <Personal Information redacted by the USI>; McCann, Bronagh <Personal Information redacted by the USI>; McClenaghan, Karen <Personal Information redacted by the USI>; Seamus McGoran Personal Information redacted by the USI >; Williamson, Sarah <Personal Information redacted by the USI>; McNicholl, Catherine <Personal Information redacted by the USI>; Thompson, Jennifer <Personal Information redacted by the USI>; Keane, Patrick <Personal Information redacted by the USI> Rajan, Nambi <Personal Information redacted by the USI>
Subject: RE: Radical Pelvic Surgery Patients

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Dear Chris

I think you may have misunderstood the point I was trying to make. I acknowledge absolutely the stresses your service is under and appreciate your frustration that investment has not happened more quickly. I also appreciate that accepting these patients was difficult for BHSCT.

What many people are not aware of is that before the Boards were stood down and the LCGs created, a major financial exercise was done to ensure that, for all the major specialities, the income to Trusts from each LCG should reflect their SBA volume. In the case of the legacy SHSSB, when that was done additional money was put into the BHSCT contract to reflect that rebalancing. That is how we have arrived at the contract volumes we have today.

The population of the south LCG has over decades had less money spent on it per head than other parts of NI (all health and social services, not urology alone). Although efforts had been made in recent years to address this inequity by way of a shift in capitation funding, that was suspended this year given the dire financial circumstances of government. That leaves the populations of the East and North with far more money being spent on them than those in the South.

I accept absolutely that by agreeing to treat these patients from the south LCG other patients will need to be displaced. That is in the best interests of complex cancer cases and was the model accepted in the urology review (albeit that is not yet implemented). However other patients referred to BCH from this area may already have chosen not to be treated at CAH for personal or clinical reasons. Patients from the part of the north LCG closest to Belfast are more likely to have been referred to BHSCT because that is the closest location for urology services. It is going to disrupt patients to be moved in this way whatever way it is done. On balance I felt that it would be fairer to move patients who (at this point) have not been funded to have their care in BHSCT, rather than those whose local commissioner has paid for their care in advance. Either way the south LCG gets no more of its residents treated in total but the south LCG patients already on BHSCT waiting lists would not be discommoded. My aim was to think about equity and fairness on behalf of the populations we serve.

Once the urology review has been fully implemented and each team has been funded to meet the needs of its natural catchment these issues will hopefully disappear.

Regards

Diane

-----Original Message-----
From: Hagan, Chris [redacted]
Sent: 22 September 2010 09:13
To: Corrigan, Diane; Armstrong, Brian; [redacted]
Cc: [redacted]; Welsh, Jennifer; Donnelly, Patricia; McCann, Bronagh; McClenaghan, Karen; [redacted]; Williamson, Sarah; McNicholl, Catherine; Thompson, Jennifer; Keane, Patrick; Rajan, Nambi
Subject: RE: Radical Pelvic Surgery Patients

Diane it's somewhat depressing to read your reply particularly with your comments about work exceeding capacity and that it is not the fault of the south LCG.

Belfast Trust urology has a finite theatre capacity and for years has performed over SBA. We make no distinction as to where these patients come from; indeed we provide an acute urology service for the vast majority of NI. When it was raised through the NI review of urology that a postcode "firewall" be created to protect teams from excess numbers of referrals from outwith catchment areas, this was rejected.

We have accommodated onto theatre lists in BCH these complex pelvic cancer cases that should be done here to meet IOG guidance. This was

done at very short notice with little or no warning and in a very unusual fashion. These patients should have been referred some time ago via the appropriate MDT and it would have been much easier to accommodate them.

The point remains though that despite the NI review of urology being signed off some time ago, and that from March 2010 all pelvic cancers should have been done in BCH, we still have not seen any monies realised by PMSID / DoH to fund this. It is also an inescapable reality that to accommodate these patients on finite lists other patients have been displaced. These displaced patients also deserve treatment in a timely fashion and we should pull together to try and achieve this by using all available resources.

Chris

-----Original Message-----
From: Corrigan, Diane [redacted]
Sent: 21 September 2010 19:43
To: Armstrong, Brian; [redacted]
Cc: [redacted] Welsh, Jennifer; Donnelly, Patricia; Hagan, Chris; McCann, Bronagh; McClenaghan, Karen; [redacted] Williamson, Sarah; McNicholl, Catherine; Thompson, Jennifer
Subject: Re: Radical Pelvic Surgery Patients

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Brian
Thank you very much for accommodating these patients. I am sure the HSCB colleagues in the Armagh office will be prepared to discuss contract issues with you. However last time I checked the BHSCT performance against SBA volumes for the south LCG seemed to be substantially below contract. In contrast it is way over for patients from the north LCG, so from your point of view the work may be exceeding your capacity - but that is not the fault of too little income from the southern office.

I think some further discussion is needed on which patients should be transferred out. Possibly north LCG residents living close to the catchment boundary with CAH?

Regards
Diane

----- Original Message -----
From: Armstrong, Brian <Personal Information redacted by the USI>
To: Rankin, Gillian <Personal Information redacted by the USI>
Cc: Corrigan, Diane <Personal Information redacted by the USI>; Hall, Stephen <Personal Information redacted by the USI>; Beth Malloy <Personal Information redacted by the USI>; Welsh, Jennifer <Personal Information redacted by the USI>; Donnelly, Patricia <Personal Information redacted by the USI>; Hagan, Chris <Personal Information redacted by the USI>; McCann, Bronagh <Personal Information redacted by the USI>; McClenaghan, Karen <Personal Information redacted by the USI>; Seamus McGoran
Williamson, Sarah <Personal Information redacted by the USI>; McNicholl, Catherine <Personal Information redacted by the USI>; Thompson, Jennifer <Personal Information redacted by the USI>
Sent: Tue Sep 21 18:05:11 2010
Subject: Radical Pelvic Surgery Patients

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It would be helpful going forward if the SHSCT patients are taken via the Regional MDM route. I understand there have been delays in realising this due to lack of Oncology support. However, as an interim measure it would be useful if a surgeon could telelink into the MDM to handover the cases. Regardless of what interim arrangements are put in place however, in the short term it is imperative that appropriate referrals are sent to the specialist surgical team in BHSCT in a timely fashion to ensure appropriate management of these patients.

Kind regards

Brian

Co-Director

Acute Services

Mobile

Personal Information redacted by the USI

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Interim Director of Acute Services
Administration Floor
Craigavon Area Hospital

27th September 2010 Ref: GR/pl/lw

Mr A O'Brien
Consultant
CAH

Dear Mr O'Brien

I am in receipt of correspondence in relation to 3 patients. In each case you have written to the patient, the General Practitioner and Mr Hagan Consultant Urologist in Belfast City Hospital.

Each of these patients has been transferred to the City Hospital for further management by Mr Hagan. I understand that you expected and wished to carry out this surgery yourself in Craigavon Area Hospital, but following contact from our Commissioner the Trust was obliged to refer the patients to Belfast.

It is of great concern that you have indicated to a patient, (in advance of a care pathway being agreed) your preferred management of the case. I believe that this puts inappropriate pressure on the receiving team and is regrettable. I understand that the transfer of these patients, with whom you may already have formed a good therapeutic relationship, was somewhat unexpected.

There is another difficult area which we are currently examining – the intravenous therapy (IVT) cohort. Since we have internal agreement that the future care pathway of these patients will be subject to a multi-disciplinary decision I do not want you to write to any of these patients individually. Any outcome of the multi-disciplinary team should be "signed off" by that team and only an agreed communication sent/provided to each patient.

Please acknowledge your agreement by return.

Yours sincerely

Dr Gillian Rankin
Interim Director of Acute Services

Craigavon Area Hospital, 68 Lurgan Road, Portadown, County Armagh, BT63 5QQ Tel No Personal Information redacted by the USI
Fax No Personal Information redacted by the USI Email Address Personal Information redacted by the USI

Subject: 20100928 Email from Bronagh McCann to SHSCT re update re Urology Patient Query [redacted] and [redacted]

From: McCann, Bronagh
Sent: 28 September 2010 08:26
To: 'martina.corrigan@[redacted]
Cc: Armstrong, Brian <[redacted] Stewart, Christine <[redacted] Hagan, Chris <[redacted]
Subject: Urology Patient Query: [redacted] and [redacted]

Hi Martina

Further to our conversation yesterday I just want to update you re the outcome of the appointments yesterday PM with [redacted] and [redacted]:

[redacted] –the patient was given a range of options for treatment, including radiotherapy. The patient has decided to go and think about these and come back to Mr Hagan. However, the provisional date of 19th October for [redacted] surgery is still held for [redacted] until such time as [redacted] has considered all [redacted] options.

[redacted] – the patient is currently an inpatient at BCH and is due to have [redacted] surgery tomorrow, Wednesday 29th September, which I believe is the same date [redacted] was scheduled for CAH, therefore incurring no delay to [redacted] treatment.

Any further queries I am happy to help.

Thanks
Bronagh

Subject: 20100928 Emails between Jennifer Welsh and Brian Armstrong BHSCT re update on urology patients

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From: Welsh, Jennifer
Sent: 29 September 2010 17:18
To: Armstrong, Brian <Personal Information redacted by the USI>; Stevens, Tony <Personal Information redacted by the USI>; Hannon, Ray <Personal Information redacted by the USI>
Cc: Hagan, Chris <Personal Information redacted by the USI>; Donnelly, Patricia <Personal Information redacted by the USI>
Subject: RE: urology patients

That's great Brian.

Can I just clarify re your discussions with Gillian – I know she is going to speak to their MD re these particular patients, but is she also going to ensure that concerns re decisions made for other patients are raised? Friday's meeting is certainly not the place, but we do need to know that she/they understand this – probably more for discussion with Chris, Ray and Tony.

Jennifer

From: Armstrong, Brian
Sent: 29 September 2010 17:06
To: Welsh, Jennifer; Stevens, Tony; Hannon, Ray
Cc: Hagan, Chris; Donnelly, Patricia
Subject: RE: urology patients

Jennifer,

Beth Malloy has agreed to raise the issue re "swop" of minor or benign procedures with Gillian Rankin at this Friday's Urology Regional Board meeting.... Chris & myself will also be in attendance..

Brian

From: Welsh, Jennifer
Sent: 28 September 2010 11:59
To: Stevens, Tony; Hannon, Ray
Cc: Hagan, Chris; Armstrong, Brian
Subject: urology patients

Tony
Update re the Urology patients we discussed yesterday.
I spoke to Chris yesterday evening, and he has had detailed discussions with the patients involved. All were discussed thoroughly at last week's regional Urology MDT, and while treatment decision may now be different than had been agreed at SHSCT, all seem to understand why this is the case. Therefore, I don't think we need to seek 2nd opinion.

In addition, Brian Armstrong has spoken to Gillian Rankin and explained about the tone/inference of the letters which were received by Chris and the patients' GPs. Gillian has apologised on behalf of SHSCT, and has advised that Dr Loughran will be writing formally to the consultant in question.
The only actions remaining are:

1. Operational discussion re "swop" of minor or benign procedures to facilitate the fact that we have taken in additional complex patients – Brian will lead on this.
2. Response to Minister's office re one of these patients – Karen McClenaghan is leading on this.

Jennifer

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Jennifer Welsh
Director of Cancer & Specialist Services

Belfast Health & Social Care Trust
Roe Villa
Knockbracken Healthcare Park
Saintfield Road
Belfast BT8 8BH

Tel: Personal Information redacted by the USI
Fax: Personal Information redacted by the USI
Personal Information redacted by the USI

Subject: 20100929 Email correspondence from Chris Hagan to Tony Stevens BHSCST

From: Hagan, Chris
Sent: 04 October 2010 21:15
To: Stevens, Tony <Personal Information redacted by the USI>; Hannon, Ray <Personal Information redacted by the USI>
Subject: RE: urology patients - confidential

Tony,
This is obviously very awkward for me – urology is a small specialty and 2 of the CAH urologists were my trainers!
I think if the surgeons concerned fully engage in the regional MDM then hopefully a lot of these issues can be avoided in the future. This would certainly be my hope. Thankfully, on Thursday, 2 of the 3 CAH urologists tele-linked with the regional MDM and referred 2 patients to Belfast.
However, a private, perhaps "off record" discussion with the CAH MD about some of these issues probably needs to happen even if just to make him aware as it is highly likely that there will be patient/ relative complaints.
Chris

From: Stevens, Tony
Sent: 29 September 2010 16:04
To: Hagan, Chris; Hannon, Ray
Subject: RE: urology patients - confidential
Chris
Thanks for this. If you are comfortable i will write to med director in southern copyying this email. I understand that situation further complicated by advise given by one consultant to patient. If you have detail on this it would be helpful. I am prepared to take strong line on this if continues, to extent of considering need for gmc referral. Happy to discuss.
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Sharon please bf when i am in office

Sent from my Windows Mobile® phone.

From: Hagan, Chris <Personal Information redacted by the USI>
Sent: 28 September 2010 15:25
To: Stevens, Tony <Personal Information redacted by the USI>; Hannon, Ray <Personal Information redacted by the USI>
Subject: RE: urology patients - confidential

Tony and Ray,
Whilst the letters sent about these patients were unhelpful, I think it misses the point with these patients and the governance issues that have been raised.
To put in a wider context, in 2002 NICE issued guidance (improving outcomes in urological cancer, IOG) specifically stating that surgeons performing <5 pelvic cancer operations / annum (radical prostatectomy and radical cystectomy) should cease. Furthermore, units performing less than 50 / year of these operations should cease immediately. In addition, there was firm guidance that all new urological cancers should be discussed at an MDT that comprised urologists, oncologists, radiologists, pathologists and CNS.

Outside Belfast, NI was slow to adopt these changes due primarily to a combination of hubris and ignorance. However, in 2007/8 with the establishment of NiCAN, NICE recommendations were largely adopted here. Since then, all hospitals bar Craigavon have referred patients to BCH for radical pelvic surgery as we are the only unit treating a population >1M and carrying out approx 80 – 90 procedures per annum. CAH still does not have a properly functioning MDT and has refused to engage with the regional MDM at BCH (all other hospitals either tele-link or attend in person). In the last 2 years, CAH have performed < 10 urological pelvic cancer operations / annum.
The Northern Ireland review of Urology signed off by the Minister of Health further cemented this guidance by stipulating that from March 2010, all urological pelvic cancer surgery should be performed in BCH. Despite this, these 5 patients were the first to be referred to BCH.
Before I saw these 5 patients, they were all discussed at the regional MDM; present were 3 urologists (Hagan/ Keane/ Rajan), 3 oncologists (Harney/ Stewart/ Mitchell), 2 radiologists (Grey / Vallely), 2 pathologists (O'Rourke/ Grey) and 1 CNS (Kelly). There was considerable variance with the management plans proposed by Craigavon Urologists and I think this is where the governance issue lies.
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The main issues are with the bladder cancer patients. All 3 have had inappropriate management plans that may well have shortened life expectancy. Failure to engage with properly constructed regional MDM would have prevented all these issues occurring. The lack of insight displayed by this surgeon who then wrote letters suggesting that there was a callous disregard for patient welfare is frankly unbelievable given the circumstances and poor management decisions.
I'm unsure if you had planned to discuss this with the CAH MD my own feeling is that he should be made aware of these governance issues and he can then act accordingly.
Chris

From: Welsh, Jennifer
Sent: 28 September 2010 11:59
To: Stevens, Tony; Hannon, Ray
Cc: Hagan, Chris; Armstrong, Brian
Subject: urology patients

Tony

Update re the Urology patients we discussed yesterday.

I spoke to Chris yesterday evening, and he has had detailed discussions with the patients involved. All were discussed thoroughly at last week's regional Urology MDT, and while treatment decision may now be different than had been agreed at SHSCT, all seem to understand why this is the case. Therefore, I don't think we need to seek 2nd opinion.

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Jennifer

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Jennifer Welsh
Director of Cancer & Specialist Services
Belfast Health & Social Care Trust
Roe Villa
Knockbracken Healthcare Park
Saintfield Road
Belfast BT8 8BH
Tel: Personal Information redacted by the USI
Fax: Personal Information redacted by the USI
Personal Information redacted by the USI

Subject: 20100929 Email from Ray Hannon to Chris Hagan re urology patients

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From: Hannon, Ray
Sent: 29 September 2010 16:50
To: Stevens, Tony <Personal Information redacted by the USI>; Hagan, Chris <Personal Information redacted by the USI>
Subject: RE: urology patients - confidential

Chris

Your email is appropriately factual

In previous roles I have written to other CD's or MD's as Tony suggests and leave it with them to resolve / discuss / debate. In my opinion the MD of the SHSCT would be best placed to investigate all this and take it forward any performance issue that arise.

We always seem to be slow at implementing national guidelines. We (the region) still haven't centralised OG surgery despite national guidance going back years so at least you now seem to have got there. In most UK areas the Strategic Health Authorities have taken more robust views and implemented change faster so I hope our SHSCB will eventually adopt a similar stance for high complexity, low volume surgery.

Ray

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Ray Hannon
Associate Medical Director
Special Services Group
Belfast HSC Trust
A Floor
Belfast City Hospital
BT9 7AB
Personal Information redacted by the USI
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From: Stevens, Tony
Sent: 29 September 2010 16:04
To: Hagan, Chris; Hannon, Ray
Subject: RE: urology patients - confidential

Chris
Thanks for this. If you are comfortable i will write to med director in southern copyying this email. I understand that situation further complicated by advise given by one consultant to patient. If you have detail on this it would be helpful. I am prepared to take strong line on this if continues, to extent of considering need for gmc referral. Happy to discuss.
tony
Sharon please bf when i am in office

Sent from my Windows Mobile® phone.

From: Hagan, Chris [redacted]
Sent: 28 September 2010 15:25
To: Stevens, Tony <[redacted]> Hannon, Ray <[redacted]>
Subject: RE: urology patients - confidential

Tony and Ray,

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To: Stevens, Tony; Hannon, Ray
Cc: Hagan, Chris; Armstrong, Brian
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Belfast Health & Social Care Trust

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Knockbracken Healthcare Park
Saintfield Road
Belfast BT8 8BH

Tel: Personal Information redacted by the USI
Fax: Personal Information redacted by the USI
Personal Information redacted by the USI

Subject: 20100930 emails between Jonathan McAleese and Chris Hagan re urology patient Personal

---

From: McAleese, Jonathan
Sent: 30 September 2010 16:50
To: Hagan, Chris [redacted]
Subject: RE: RE PT Personal

Ok that's helpful.
When I meet up with him in Craigavon I'll go through all the options with him if I can to try to get realistic expectations.

jonathan

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hris
ber 2010 16:48
onathan
on'; O'Sullivan, Joe
RE PT Personal

Jonathan
He has quite extensive retroperitoneal LN disease which has probably been underestimated from CAH radiology reports. Arthur Grey reviewed all radiology at central MDM last week.

Obviously if he is CR post chemo then surgery is an option; however I suspect palliative RT post chemo is going to prove to be the most likely option.

Chris

From: McAleese, Jonathan
Sent: 30 September 2010 16:19
To: Hagan, Chris
Cc: 'Porter, Alison'; O'Sullivan, Joe
Subject: RE PT Personal

Just to let you know. Joe passed on the referral on [redacted] to me today. I don't think Joe is planning to see him as you have alluded to in your letter to Mr O'Brien
I would plan to see him at my clinic in Craigavon to assess him for systemic chemotherapy. I understand the plan is then to rescan to look at the mesenteric lymph nodes to see if surgery might be appropriate.

jonathan

From: Hagan, Chris

Sent: 18 June 2023 18:12

To: Hagan, Chris

Subject: Fwd: Thanks

---

chris

Chris Hagan

Medical Director

From: Corrigan, Diane <[redacted]
Sent: Sunday, October 3, 2010 6:19:22 PM
To: Hagan, Chris <[redacted]
Subject: Thanks

"This e-mail is covered by the disclaimer found at the end of the message."

Dear Chris
I meant to speak to you at Friday's meeting but did not get an opportunity. I wanted to thank you and your colleagues for accepting the CAH cancer transfers at such short notice and operating so promptly on the first couple.

I heard from Mark Fordham that letters were sent from the CAH consultant to the patients' GPs, the patients and yourself which were not helpful. When you were going out of your way to do something which was in the best interests of the patients concerned that must have been hard to take. Things will get better.

Thanks once again.

BW
Diane

****

Note: For continuation of email trail found at WIT-99145 to WIT-99147, see WIT-100349 to WIT-100351. Annotated by the Urology Services Inquiry.

Subject: 20101004 Email from Tony Stevens to Chris Hagan re chat with Paddy Loughran CAH MD

From: Stevens, Tony
Sent: 04 October 2010 22:34
To: Hagan, Chris <Personal Information redacted by the USI>; Stevens, Tony <Personal Information redacted by the USI>; Hannon, Ray <Personal Information redacted by the USI>
Subject: RE: urology patients - confidential

Chris. I will be content to chat to paddy loughran informally. If that does it fine. If not and if your concerns persist then we would need to consider next steps.
tony

Sent from my Windows Mobile® phone.

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Ray Hannon's email address >
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Tony
Update re the Urology patients we discussed yesterday.
I spoke to Chris yesterday evening, and he has had detailed discussions with the patients involved. All were discussed thoroughly at last week's regional Urology MDT, and while treatment decision may now be different than had been agreed at SHSCT, all seem to understand why this is the case. Therefore, I don't think we need to seek 2nd opinion.
In addition, Brian Armstrong has spoken to Gillian Rankin and explained about the tone/inference of the letters which were received by Chris and the patients' GPs. Gillian has apologised on behalf of SHSCT, and has advised that Dr Loughran will be writing formally to the consultant in question.
The only actions remaining are:

1) Operational discussion re "swop" of minor or benign procedures to facilitate the fact that we have taken in additional complex patients – Brian will lead on this.
2) Response to Minister's office re one of these patients – Karen McClenaghan is leading on this.

Jennifer
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