SHERIFFDOM OF LOTHIAN AND BORDERS AT EDINBURGH
IN THE ALL-SCOTLAND SHERIFF PERSONAL INJURY COURT

[2022] EDIN 41

PIC-PG10-20

JUDGMENT OF SHERIFF JOHN K MUNDY

in the cause

NORMAN ADAMSON

Pursuer

against

HIGHLAND HEALTH BOARD

Defender

Act: Markie, Advocate, instructed by Morton Fraser LLP, Edinburgh
Alt: Bennett, Advocate, instructed by Central Legal Office for NHS

Edinburgh, 11 October 2022

The sheriff, having resumed consideration of the cause, finds as follows:

Findings in fact

1. The pursuer is Norman Adamson and he resides on the Isle of Mull. His date of birth is 8 February 1953.

2. The defender is Highland Health Board, a health board having its headquarters at Assynt House, Beechwood Park, Inverness IV2 3BW.

3. In around 23 July 2015, the pursuer attended his general practitioner complaining of repeating episodes of haematuria without signs of urinary infection or stones. An

ultrasound scan was arranged, a 5 cm x 4 cm bladder mass was detected, and the right ureteric orifice was obscured.

4. On 14 September 2015, the pursuer underwent a cystoscopy, which demonstrated a large papillary mixed appearance bladder tumour. The size of the largest tumour was greater than 30mm. The tumour sites included the right ureteric orifice, trigone and bladder neck. The pursuer underwent a transurethral resection of the bladder tumour. A follow-up cystoscopy was arranged.

5. On 2 November 2015, a cystoscopy was performed, and biopsies taken from the area of the previous tumour resection site. Extensive inflammation and necrosis were identified but no residual tumour. The anterior bladder neck, the papillary area anteriorly and the bladder neck had an overall appearance slightly suggestive of papillary non-invasive tumour, but this was not regarded as diagnostic.

6. The foregoing procedures were carried out under the care of Mr David Hendry, Consultant Urologist, at the Queen Elizabeth University Hospital, Glasgow.

7. On 20 November 2015, the pursuer met with Mr Hendry and discussed with him his treatment options. Those were either an early radical cystectomy or intravesical Bacillus Calmette-Guerin ("BCG") immunotherapy. The pursuer's results, following cystoscopy, had been discussed by the Glasgow Uro-Oncology Multi-Disciplinary Team, and it was agreed that the pursuer would be suitable for either of those treatments. The pursuer opted for the BCG treatment, as he wished, if at all possible, to avoid a radical cystectomy involving the removal of his bladder. Mr Hendry explained to the pursuer that if on follow-up, he had a recurrence, then he would in all likelihood require a radical cystectomy. Mr Hendry explained to the pursuer what was involved in the BCG treatment.

8. Intravesical immunotherapy aims at producing a massive local immune response. BCG intravesical installation is a procedure whereby BCG is slowly introduced into the bladder and allowed to remain there for a specific length of time before the bladder is voided. It is performed to expose the tissues of the bladder to the solution. When instilled into the bladder BCG triggers an immune response in the mucosa with the aim of killing cancer cells. BCG treatment is the most common intravestical immune therapy for treating early stage bladder cancer. Possible and common side effects of the treatment include an irritated bladder, the urge to pass urine more often than usual, blood in the urine, flu-like symptoms for 24-48 hours after each treatment and painful joints. Severe complications occur in less than 5% of patients. There is also an extremely small chance that some of the BCG can enter the patient's system. Disseminated infection following BCG intravesical treatment is extremely rare and has been reported as occurring in 0.4 of patients, more recent estimates being that it occurs in about 1 out of 15,000 patients. Where the patient becomes septic, has a fever over 39.5C or a persistent temperature of over 38.5C for more than 24 hours, BCG osis can be suspected.

9. Treatment is usually given by a Urology Nurse Specialist. The nurse will clean the genital area with a sterile solution. A small flexible catheter will then be inserted into the patient's bladder. This will remove any urine that is still in the bladder. Lubrication gel is applied to assist the passage of the catheter. The BCG solution is then run into the bladder through the catheter tube. The tube will then be removed. The solution will be left in the bladder for a period of time, which is generally recommended to be two hours, but can be less. After the period has elapsed, the patient is asked to void their bladder, in other words pass water to empty the bladder.

10. The treatment is usually given once a week for six weeks. After this period, some patients have further doses (booster treatments).

11. Following the pursuer's decision to opt for BCG treatment, he was referred to Urology Nurse Specialist, Margot Gent-White at the Lorn & Islands Hospital in Oban, which was the most convenient hospital for the pursuer. Mr David Hendry, Consultant Urological Surgeon, the consultant in charge of the pursuer's care, sent a letter to Ms Gent-White on 20 November 2015 with a view to arranging the treatment. He instructed six induction treatments following which he would carry out a cystoscopy.

12. The pursuer attended for his first treatment on 10 December 2015 and underwent further BCG induction course therapies on 15 December 2015, 22 December 2015, 6 January 2016, 13 January 2016 and 20 January 2016. On each of these occasions, the dwell time for the BCG solution in the bladder was approximately one hour.

13. On 10 December 2015, the procedure was carried out without any difficulty. On 15 December 2015, the second treatment was carried out again without difficulty. On 22 December 2015, Nurse Gent-White encountered slight resistance at prostate level. Nurse Gent-White decided to call upon Dr Das a General Surgeon at the hospital for assistance. He inserted a 16 Fr Tiemann catheter and there were no problems in completing the catheterisation.

14. On 6 January 2016, Nurse Gent-White encountered slight resistance at the prostatic urethra but was able to successfully complete the catheterisation for the purposes of the treatment.

15. On 13 January 2016, the treatment was given without any problem.

16. On 20 January 2016, Nurse Gent-White encountered a resistance at the mid urethra and again at prostate level. Dr Das was again contacted and used a Tiemann catheter as

before. The catheter was successfully inserted with slight resistance only. There was slight trauma bleeding.

17. For the treatments, Nurse Gent-White used a size 12 Fg catheter, which was smaller and allowed easier insertion particularly at the prostatic urethra. She also used a gel as lubricant to assist in the process.

18. The BCG solution used on each occasion was called OncoTICE.

19. On 4 March 2016, the pursuer was reviewed by Mr Hendry at Glasgow who performed a first check cystoscopy following the first six BCG treatments. A bladder tumour resection and biopsies were performed. There was evidence of recurrent tumours. The pursuer was keen to avoid a radical cystectomy and Mr Hendry considered it to be reasonable to give three booster BCG treatments before deeming the treatment to have failed. He therefore communicated with Nurse Gent-White once again and requested three further instillations of BCG with a two hour dwell time with a view to performing a cystoscopy six to eight weeks after that. A letter with that request was sent to Nurse Gent-White on 8 April 2016. The referral for booster treatment was made following discussion of the options with the pursuer.

20. On 13 April 2016, the pursuer attended once again with Nurse Gent-White at the Lorn & Islands Hospital in Oban to receive the first of the intravesical treatments with OncoTICE. As the catheter was inserted, again using a size 12 Fg and lubricant gel, a slight resistance in the mid urethra was encountered. However, Nurse Gent-White was able to insert the catheter into the bladder carefully without further difficulty. She did not consider it necessary to call upon Dr Das on this occasion. The treatment was commenced at around 10:30am. At around 11:30am the pursuer complained of feeling cold and shivery. Nurse Gent-White called upon Dr Das to review the pursuer who was given 1g of paracetamol. He

felt better by around 11:50am. In the meantime, the BCG solution was retained within the bladder for a total of around two hours after which the bladder was voided by the pursuer going to the toilet. There was a small amount of bleeding in the urine. The pursuer felt nauseous but insisted on going home against the advice of Nurse Gent-White and Dr Das. They advised him to stay overnight in hospital for observation. The pursuer was advised by Nurse Gent-White to see his GP the following morning and to return for review by Nurse Gent-White the following week.

21. Nurse Gent-White had been aware, prior to the treatment on 13 April 2016, through communicating with Mr Hendry that the pursuer had a slight stricture in the urethra. However, this was not considered by Mr Hendry to be a contra indication to the booster treatment by way of a catheter.

22. Resistance in the mid urethra when a catheter is inserted is not uncommon and does not necessarily indicate urethral damage. On 13 April 2016, the pursuer did not report discomfort or pain during the insertion of the catheter. Discomfort and/or pain would be expected if the catheterisation had been traumatic or if injury had been sustained to the urethra. On that occasion when the catheter was removed following insertion of the instillation, no blood was evident. The appearance of blood at this stage would be an indicator of a traumatic catheterisation.

23. The flu-like symptoms experienced by the pursuer around an hour after the instillation are a common side effect of the treatment. The appearance of blood in urine (haematuria) when the bladder is voided after the dwell time – is also common and not unexpected. This is because the BCG solution has the effect of causing inflammation to the inner lining of the bladder and can lead to bleeding.

24. After the pursuer left the hospital, he experienced haematuria and flu-like symptoms. Nurse Gent-White contacted the pursuer on a number of occasions by telephone after 13 April 2016. On 15 April 2016, he reported to her that his urine was slightly bloodstained and that he was still feeling very flu-like. He was advised to continue with his prescription of paracetamol. On that day Nurse Gent-White contacted the pursuer's GP advising that Mr Hendry wished the patient to be put on ciprofloxacin, a broad spectrum antibiotic which was effective in relation UTI's. Nurse Gent-White had made Mr Hendry aware of the pursuer's symptoms.

25. On 20 April 2016, Nurse Gent-White contacted the pursuer again who reported that he was not feeling "100%" and very lethargic. Further booster treatment was deferred.

26. On 27 April 2016, Nurse Gent-White again contacted the pursuer who reported that he was still not feeling well. She reminded him to see his GP. He had not seen his GP following the first booster appointment on 13 April 2016 despite repeated requests by Nurse Gent-White for him to do so.

27. Nurse Gent-White had been in touch directly with the pursuer's GP on 15, 20 and 27 April 2016 as she was concerned for the pursuer. The pursuer attended his GP on 28 April 2016 who took blood. The results were available on 29 April 2016, when the pursuer again attended his GP. The bloods showed infection.

28. Mr Hendry was able to access the results of the blood tests on 29 April 2016 and he thought it best to admit the pursuer to hospital for further investigation and treatment. He was admitted to the Queen Elizabeth University Hospital in Glasgow on 2 May 2016.

29. On admission, the pursuer was seen by Mr Hendry who suspected BCG osis. After further tests the diagnosis was confirmed and treatment for BCG osis was commenced on 8 May 2016. The diagnosis was likely disseminated BCG infection with pancytopenia

although there was no positive microbiology for TB. The pursuer was managed with intravenous antibiotics and commenced on anti TB treatment. The pursuer's condition improved and he was discharged from hospital on 19 May 2016.

30. In September 2016, the pursuer underwent a cystoscopy, which showed a transitional cell carcinoma grade 2 at the bladder neck. Given the presence of persistent tumour, Mr Hendry discussed with the pursuer proceeding to a radical cystectomy. This course of action was agreed and a radical cystectomy was performed on 7 December 2016. The final pathology showed no residual tumour in the bladder.

31. When Mr Hendry performed the cystoscopy in September 2016, there was no evidence of there having been a dramatic catheterisation on 13 April 2016. Evidence such as scarring would be expected if an injury such as a mucosal breach had occurred.

32. The pursuer developed systematic BCG infection following his first booster dose of intravesical BCG on 13 April 2016, caused by the spread of BCG from his urinary tract into the systemic circulation.

33. The pursuer made a complete recovery from his systemic BCG infection after about 6 months. After the development on the infection, he was treated for around six months with antibiotics.

Findings in fact and law

34. It has not been proved that Nurse Gent-White deviated from the usual and normal practice of a Urology Nurse Specialist when she treated the pursuer on 13 April 2016 or that she adopted a course, which no specialist urology nurse of ordinary skill would have taken if they had been acting with ordinary care.

35. It has not been proved that Dr Das deviated from the usual and normal practice of a middle grade general surgeon in treating the pursuer on 13 April 2016, or that he adopted a course that no general surgeon of ordinary skill would have taken if they had been acting with ordinary care.

36. It has accordingly not been established that either Nurse Gent-White or Dr Das were negligent in their treatment of the pursuer on 13 April 2016.

37. While it is likely that the development of BCG osis was causally connected in some way with the catheterisation procedure carried out on 13 April 2016, the mechanism is not known, and in any event, it is not established that this was as a result of the negligence of either Nurse Gent-White or Dr Das.

38. It is not established that there is any causal connection between the alleged failures of either Nurse Gent-White or Dr Das to refer the pursuer to hospital for evaluation, and in particular an infectious diseases control unit, and any loss, injury or damage.

39. *Separatim*, *esto* the pursuer is entitled to damages, an appropriate sum to reflect solatium would be £10,000, all of which would be attributable to the past with interest thereon at the rate of 4% per annum from 13 April 2016.

Finding in law

40. The pursuer not having suffered loss, injury and damage as a result of the fault and negligence of the said employees, for which the defender is in law responsible, the defender is entitled to decree of absolvitor.

INTERLOCUTOR

THEREFORE, sustains the third and fourth pleas in law for the defender; repels the first plea in law for the pursuer; assoilzies the defender from the craves of the writ; meantime reserves all questions of expenses and appoints a hearing thereon on a date to be afterwards fixed.

Note

[1] This is an action of damages at the instance of the pursuer against the defender, a health board, on the basis of the alleged clinical negligence of two of their employees, a Urology Nurse Specialist and a General Surgeon. It arises from their treatment of the pursuer when he attended at the Lorn & Islands District Hospital, Oban on 13 April 2016.

[2] The facts of the matter are set out in detail in my findings in fact. I will not rehearse those details. In summary, the pursuer was diagnosed with bladder cancer in around September 2015 and following surgery, he was advised by his treating doctor Mr David Hendry, Consultant Urological Surgeon, of the treatment options, which were either an early radical cystectomy (bladder removal) or intravesical BCG therapy. The pursuer opted for the latter and was referred by Mr Hendry to Nurse Gent-White in the said hospital in Oban for that treatment. The treatment involves the instillation of a BCG solution by way of a catheter, inserting it through the urethra into the bladder. He attended for six treatments between 15 December 2015 and 20 January 2016. Following a further procedure on 4 March 2016, carried out by Mr Hendry the pursuer was referred once again to Nurse Gent-White for three booster sessions of BCG therapy. The first of those booster sessions occurred on 13

April 2016 and it is in relation to the events of that treatment that this case arises. Following that day the pursuer went on to develop something known as BCG osis, which ultimately required hospitalisation at the Queen Elizabeth University Hospital in Glasgow. Fortunately for the pursuer has now recovered from that episode.

[3] After sundry procedure, the matter came before me for proof in which evidence was heard over five days with a subsequent day set aside for submissions, following which I made avizandum.

[4] At the proof Mr Markie, Advocate appeared on behalf of the pursuer, and Ms Bennett, Advocate, represented the defender. Liability, causation and quantum of damages were all in dispute. There was a joint minute of admissions, which agreed medical records and such like documents. It also agreed that the reports of the medical experts were to be treated as evidence in chief of those witnesses except for the report of a Professor Clifford Leen, Consultant Physician which was to be treated as his evidence without being spoken to by him. He did not give oral evidence.

[5] In the pursuer's proof the following witnesses were called:

1. The pursuer, Norman Adamson;
2. Nurse Margot Gent-White;
3. Dr Diwa Das;
4. Sally-Ann Dickinson, Registered Nurse, a Nursing Expert;
5. Mr Amir Kaisary, Consultant Urological Surgeon.

[6] In the defenders proof the following witnesses were called:

1. Anthony Barrett, Nursing & Healthcare Consultant;
2. Professor Samuel McLinton, Consultant Urological Surgeon;
3. Mr David Hendry, Consultant Urological Surgeon.

[7] As explained the evidence of Professor Clifford Leen, Consultant Physician in Infectious Diseases, was agreed to be represented by his report lodged in process.

The pursuer

[8] The pursuer gave evidence as to the history of his diagnosis of bladder cancer and subsequent treatment under the supervision of Mr Hendry, Consultant Urologist. The circumstances giving rise to his treatment with BCG intravesical immunotherapy ("BCG") were uncontroversial. There was an issue of whether or not the pursuer was provided with a patient information leaflet in relation to the solution, which would be instilled into his bladder called OncoTICE. However, he accepted that he had discussed in general terms the risks and benefits of BCG treatment with Mr Hendry in November 2015. He also accepted that the BCG treatment was opted for by him, as he was keen to avoid a radical cystectomy involving the removal of the bladder. I think it is fair to say that the pursuer accepted that it was unlikely that the BCG treatment would be successful as he explained that Mr Hendry was not very hopeful that it would work but that it was an option worth trying.

[9] The pursuer spoke to his six induction treatments between 10 December 2015 and 20 January 2016. When the first treatment was administered on 10 December 2015, there were no difficulties and according to the pursuer, nothing untoward happened. On the second visit on 15 December 2015, again there were no problems. On the third visit on 22 December 2015, the pursuer indicated that it did not go as smoothly. There was some resistance at prostate level and Nurse Gent-White called upon the resident General Surgeon Dr Das to carry out the procedure with a different catheter, which had a curved end, and he was able to negotiate the prostate and successfully insert the catheter into the bladder. The pursuer felt that it was uncomfortable. On the fourth occasion on 6 January 2016, the pursuer did

not recall any problems although Nurse Gent-White's nursing notes indicate that there was "slight resistance at the prostatic urethra". He thought it was fairly straightforward. On the fifth visit on 13 January 2016, again there appeared to be no difficulty whatsoever with the procedure. On the sixth visit on 20 January 2016, the pursuer indicated that the catheter would not go all the way in. On that occasion, the nurse stopped and called upon Mr Das to insert a catheter. Again, he used a slightly different type. The nursing notes record that there was resistance met at the mid urethra and again at prostate level. However, again, Dr Das was able to complete the insertion of the catheter and the procedure was carried out to completion. The pursuer indicated that on this last occasion it was painful. The nursing notes record that there was "slight resistance only" when Dr Das inserted the catheter with "slight trauma bleeding". The pursuer did not feel unwell. After the six treatments, Nurse Gent-White communicated with Mr Hendry and the pursuer saw Mr Hendry once again who following surgical examination re-referred him to Nurse Gent-White for three booster sessions of BCG treatment. We then come to 13 April 2016, the day of the first booster session.

[10] When the pursuer gave evidence about this, he indicated that Nurse Gent-White encountered some resistance in inserting the catheter and enquired of the pursuer whether she should proceed. He said it was up to her as she was in charge of the treatment. He said that Nurse Gent-White carried on and forced the catheter injuring him and causing the BCG solution to be introduced into his general system. He said he immediately went into shock and began uncontrollable shaking. It was a very unpleasant experience. He was hot and cold. Nurse Gent-White became alarmed and contacted Dr Das who came in and suggested that the pursuer take paracetamol. He thought that Dr Das showed a lack of concern. He indicated that he wanted to get out of the hospital and that there was no offer of admitting

him. He indicated that Nurse Gent-White was concerned but Dr Das was not. When he voided his bladder following the procedure, he produced an amount of blood. The pursuer was clear in his evidence at this point that when the catheter was forced past the obstruction that it was painful. He gave evidence under reference to the nursing notes that Mr Hendry had mentioned that the pursuer had a slight stricture but the pursuer did not remember Mr Hendry telling him that although he may have done. The pursuer indicated that he did not know what had happened at the time. The pursuer said that on his trip home to Mull he spent his time in the toilet cubicle and passed a great deal of blood. After he got home, he was contacted by Nurse Gent-White and ultimately went to his doctor following which he was admitted to the Queen Elizabeth University Hospital in Glasgow at the insistence of Mr Hendry. He was admitted there on 2 May 2016 being discharged on 19 May 2016.

[11] In cross examination he accepted that when the catheter was removed following instillation of the BCG solution there was no bleeding and confirmed that following instillation of the solution he voided his bladder after two hours, the period recommend by Mr Hendry. The induction treatments involved the solution remaining in the bladder for one hour only. When questioned under reference to the nursing notes, where it is mentioned that he "insisted on going home" he accepted that the suggestion was that he stay but he did not take that to mean that he should be admitted. He accepted that despite the advice from Nurse Gent-White to attend his GP the day following the treatment he did not do so until 28 April 2016. When questioned under reference to a complaint he made to NHS Highland in July 2016, he accepted that it was only after approximately an hour that he started to feel unwell following insertion of the catheter on 13 April 2016. In other words, he did not immediately feel unwell. He accepted this again in re-examination. He confirmed

that following his subsequent treatment he had now no symptoms of BCG osis and had been discharged from treatment in that regard.

Nurse Gent-White

[12] The witness had qualified as a State Registered Nurse in 1972 and had around 30 years' experience as a Urology Nurse Specialist. She had significant experience in male catheterisation and provided BCG therapy to around 20-30 patients prior to the pursuer's treatment. She explained the technique involved in the therapy. She employed a strict aseptic technique, the application of lubricant and the gentle insertion of the catheter tube through the urethra into the bladder. She explained the difference in sizes of catheter. She generally used a size 12 Fg (which has a diameter of approximately 4mm). She did so on the occasions of the treatment of the pursuer. For the purposes of the treatment, the catheter would be gently inserted into the urethra passing into the bladder when urine would drain back. For the purposes of BCG therapy once the urine was drained the BCG would be installed, the catheter removed and the solution left in the bladder for a period of time. The bladder would then be voided after that time had elapsed by the patient going to the toilet. The size of catheter she used was smaller than some, easier to insert and more comfortable. If directed otherwise by a doctor she would use an alternative catheter. She would stop the process of catheterisation if there was discomfort or the patient felt unwell. If she met strong resistance, she would stop and seek advice. If there was slight resistance she indicated that she could proceed if the catheter goes in smoothly. She would never force the catheter past the point of resistance. If she could not get the catheter inserted, she would not proceed with the BCG installation. If the patient was unwell or had an infection, she would not proceed with the installation. She agreed that traumatic catheterisation is a contra indication

to proceeding with BCG installation. However, she would not get to that stage. She would not push the catheter in if it would cause trauma. If patients had a urethral stricture and she was aware of that she would always take extra care including using plenty of the lubricant gel. If an injury was caused she would not proceed with the installation of BCG solution. When it came, down to resistance, it was a matter of the feeling the practitioner got (whether the resistance was strong or slight) and that came from experience and from clinical judgement.

[13] In relation to the treatment on 13 April 2016, her recollection was that the usual procedure was adhered to. She noted slight resistance but the catheter passed easily after that. Urine drained from the catheter and the BCG solution was installed. The catheter was then removed. There was no blood in the urine that drained and no blood was noted on the catheter when it was removed. She said that after around 45 minutes, the pursuer became shaky and she put him to bed. She took observations, which were normal. She called for Dr Das who assessed the pursuer. He prescribed paracetamol and after about 20 minutes, the pursuer's symptoms settled down. The pursuer retained the BCG instillation in his bladder for approximately two hours prior to voiding. When he passed urine, she noted some blood in the toilet but nothing to be alarmed about. Blood in the urine could be expected sometimes after BCG treatment. She said that both she and Dr Das advised the pursuer to stay in hospital overnight in order to monitor him, including checking his bloods, and to make sure he was alright. The pursuer however did not want to stay. She escorted the pursuer to his friend's car and advised him to see his GP in the morning and to take paracetamol. She contacted the pursuer's GP and Mr Hendry that day and informed them about what had happened. She contacted the pursuer later that day and he advised that he had passed blood on the ferry. She contacted him again on or about five or six occasions, as

she was concerned that he had not been in touch with his GP and was still not feeling 100%. She was concerned that he was not adhering to her advice.

[14] Nurse Gent-White explained that flu-like symptoms were relatively common following BCG instillation, which is why paracetamol was recommended. However, she thought that the pursuer may have had a bacteraemia attack, which can occur with catheterisation. That is why she wanted him to stay in hospital for observation. It did not cross her mind that the symptoms he displayed were indicative of BCG osis. She could not know how serious the symptoms were because he did not stay in hospital for observation and monitoring. Had he stayed in hospital the pursuer would have had blood pressure checks, his bloods taken, his temperature, heartrate and urine monitored on a regular basis.

[15] She confirmed that on two occasions during the induction treatments she called upon Dr Das for assistance when she had met resistance, which made her uncomfortable about proceeding. She did not want to cause damage so asked Dr Das for advice. The resistance found on 13 April 2016 was mid urethra, not prostate level. She felt comfortable with the treatment and successfully inserted the catheter without any discomfort or upset to the pursuer. She was aware from the letter from Mr Hendry that the pursuer had a slight stricture, which was found on the last surgical procedure. She would always take care and in light of this information, she would take extra care. The mere presence of a stricture would not be a contra indication to catheterisation and BCG therapy. Strictures were quite common. Had she had any doubt about the position on 13 April 2016, she would have called upon Dr Das as she had done previously. She accepted that she did not record in the nursing notes her advice and that of Dr Das that the pursuer was to stay in hospital. She thought she had. She did however record that the pursuer "insisted" on going home, which is consistent with her recollection. She did not accept that she had failed in her duty of care

towards the pursuer either by not stopping the catheterisation when she felt slight resistance or by not contacting Dr Das when she encountered resistance.

Dr Das

[16] Dr Das explained that he was a "middle grade surgeon" in the hospital at Oban. He was a general surgeon in a rural hospital. He was not a Urologist and had no experience in nor responsibility for delivering BCG therapy. He explained that he had had an understanding of BCG therapy and a theoretical understanding of the risks of treatment including urinary tract infection (UTI) which was quite common, minor episodes of migraine and theoretically and rarely BCG osis or tuberculosis. He was experienced in catheterisation and explained the procedure in relation to that in general terms. He assisted junior doctors or the Urology nurse with difficult catheterisations. Contra indications to proceeding with catheterisation would be where there was a previous history of trauma, where it was painful or where there was blood. In relation to strictures he indicated that they could pose a challenge depending on the severity of the stricture and that could dictate the size of the catheter used. If there was resistance and the catheter was not going in then you would stop the procedure, but the meeting of resistance did not mean that the procedure should not proceed. It would depend upon the extent of that resistance.

[17] In relation to his involvement with the pursuer, he recalled Nurse Gent-White asking for his assistance with catheterisation on 22 December 2015, when there had been slight resistance at prostate level, which prompted her to call him. He explained that in his experience this resistance at prostate level was almost always encountered in men. He was able on that occasion to pass the catheter. Again, on 20 January 2016, he was called upon to assist, as there was resistance at prostate level. He chose a 16 Fg Tiemann catheter. He did

not recall resistance at the mid-urethra but did at prostate level. He did not witness the "slight trauma bleeding" referred to in the nursing notes.

[18] On 13 April 2016, he was asked by Nurse Gent-White to assist the pursuer. She had explained to him the pursuer's symptoms and observations (which were within normal range). His advice was that the symptoms were common and usually settled down. He asked him to stay in hospital overnight so that they could monitor him and if all was well, he could travel on to his home in Mull. By common symptoms, he meant flu-like symptoms. The thought of BCG osis did not cross his mind but UTI did because "rigors" can happen with a UTI. When Dr Das assessed the pursuer, he had already had the catheter removed and the instillation was in the bladder. He saw the pursuer before the bladder was voided. He explained that had the pursuer stayed in hospital, as he was advised to do, he would have been monitored.

Sally-Ann Dickinson

[19] This witness was a Senior Registered General Nurse who spoke to her report. She has significant experience in providing expert witness evidence. Her listed fields of experience do not include Urology. She explained however that she had experience in urological nursing when she worked in general surgery in 1996 and had experience of BCG therapy at Hinchingbrooke Hospital (1987-1990). At the outset of her evidence, she said that she agreed with the conclusions of the pursuer's expert Dr Kaisary from a senior nursing perspective. Her criticisms of Nurse Gent-White are set out in the conclusions in her report at 6.1 and following.

[20] On the issue of catheterisation and when it was appropriate to stop, there were no generalities. It would depend upon individual presentation, past history plus any concerns

the nurse had clinically. It was, she accepted, a matter of judgement. Male catheterisation was an extended competency for nurses due to the associated risks of trauma occurring with incorrect technique and potential scope for complex catheterisation (due to factors such as enlargement of the prostate and urethral stricture). It was necessary for most nurses to undergo extended training and obtain signed-off competence in this skill prior to performing male catheterisation. It would therefore be expected that a nurse practitioner who routinely carried out catheterisations would be highly skilled in this area. In order to minimise trauma to the urinary tract the catheter should never be forced where there is resistance. Urethral trauma can be secondary to the use of poorly lubricated catheter or incorrect technique such as forcible catheterisation. Typically, the first sign that trauma has occurred is bleeding. Forcing a catheter past the point of resistance is not only painful/distressing for the patient but can also cause significant injuries ranging from a breach in the tissue/mucosal tare to more serious false passages (perforations) which are associated with an infection, urethral stricture and subsequent surgical management. If bleeding is observed post-catheterisation due to suspected trauma, the attending nurse should observe the output from the catheter and document the severity of the haematuria i.e. blood in urine. If the bleeding is severe and consistent, advice from the medical team should be sought. Severe bleeding warrants an urgent medical opinion. National clinical guidelines and protocols dictated that catheters should not be forced on application as there is a risk of trauma or false passages being created. Further, the guidelines state that should there be any bleeding seen from catheterisation then medical advice should be sought by nursing staff. Further, urethral stricture may make catheterisations problematic. Haematuria (within 24-48 hours) would be caused if the bladder was empty or the catheter

was in the wrong place e.g. in the urethra or in a false tract. False tracts may develop after repeated cystoscopy or bladder surgery.

[21] The witness considered that Nurse Gent-White breached her duty of care to the pursuer in not referring him for medical assessment before proceeding with catheterisation on 13 April 2016 as she had previously done when resistance was felt and by not immediately referring him for more specialist medical assessment at hospital with the developing symptoms an hour after the BCG application and/or two days later upon enquiring about his condition by telephone given the ongoing symptoms. In addition, she should have informed his treating consultant Mr Hendry urgently of the occurrence of the incident and the symptoms to seek treatment advice.

[22] In relation to the induction course of treatment, she said that Nurse Gent-White had appropriately escalated the treatment by bringing in Dr Das when she had experienced resistance on catheterisation. This is what she should have done, she said, on 13 April 2016. Initially, her position appeared to be that she should have called upon Dr Das when she encountered resistance but her position had developed (in cross examination) when she appeared to indicate that she should not have proceeded with the catheterisation at all in a case like the pursuer's where there had been a history of difficult catheterisations. This was in spite of the fact that Mr Hendry had referred the pursuer for booster treatment. She went further and suggested that if there was any resistance a nurse should not proceed with the catheterisation in the circumstances of the pursuer. This was somewhat at variance with her evidence that it depended upon the individual circumstances.

[23] She disagreed with the opinion of the defender's nursing expert Anthony Barrett that there was no evidence within the documentation that there was any suggestion of negligence in catheterisation during the BCG treatment.

Anthony Barrett

[24] Mr Barrett, who was interposed at this juncture, was the defender's nursing expert. He is a Band 8a Urology Advanced Nurse Practitioner having practiced urology for 28 years. He had previously been ward manager in urology over a period of nine years and in 2016 took on the Lead Urology Clinical Nurse Specialist position. He has significant experience in BCG therapy. He spoke to his report and also the NHS Highland Protocol, Patient Information Leaflet and also commented upon Nurse Dickinson's report.

[25] In the conclusions of his report, he indicates that there is no evidence within the documentation reviewed that there is any suggestion of negligence in catheterisation during the BCG treatment. Conversely, when an issue with the catheterisation was identified, as on 22 December 2015, when "slight resistance at prostate level" was identified it was escalated to Dr Das who performed the catheterisation with a specialist Coude tip catheter. "Slight resistance" was also reported on 6 January 2016, but no other complications at this point. A specialist catheter was not required as being required. Subsequently, the catheterisation for the fifth dose on 13 January 2016, reported no issues with a regular size 12 catheter. On the sixth dose being administered however, a difficulty was identified in that "resistance felt mid urethra and again at prostate". This was again appropriately and swiftly escalated to Dr Das who successfully catheterised the pursuer with a size 16 Tiemann tipped catheter although there was "slight resistance" and "slight trauma bleeding". In the opinion of Mr Barrett, there was no evidence in those statements to suggest negligent catheterisation and Nurse Gent-White had appropriately escalated her apprehensions to a senior member of the team when she identified a difficulty. On 13 April 2016, while "slight resistance mid urethra" is noted and also that "Mr Hendry had mentioned the patient had a slight

stricture", there was no indication of any significant problems or complications and the BCG was retained for the planned two hours. There was no evidence to suggest that the catheterisation was negligent in its execution. There was minimal documented resistance to pressure when the strictured area was identified, therefore minimal force was utilised to negotiate this area, with no indication that any alternative methods or equipment should have been identified or utilised. Strictures are not uncommon after multiple instillations and catheterisations and from his personal experience most could be safely negotiated with relative ease especially when consideration is given to the relatively small size of catheter used – size 12 approximately 4mm in diameter. There was no identifiable bleeding reported and no evidence that the urethra had been penetrated or damaged at this time as would be expected within the definition of traumatic catheterisation. Such issues would undoubtedly have caused the pursuer severe and sudden urethral pain and there was no evidence that he experienced this during catheterisation. Subsequently, the BCG solution was retained for the optimum time of two hours, which would have been extremely painful and difficult for the pursuer to have achieved if the catheterisation had been traumatic and had caused urethral damage or perforation. After the pursuer presented with symptoms of shivering and nausea, Nurse Gent-White correctly and appropriately escalated the incident to a senior clinician. The flu-like symptoms quickly resolved and the pursuer went home in spite of medical advice to stay overnight. Nurse Gent-White regularly maintained contact with the pursuer to check on his condition in excess of the expectations that would routinely be expected. BCG osis is, according to the witness, a rare but severe complication of BCG intervesical treatment. Mr Hendry had identified the stricture at previous cystoscopies but had not given any indication that a specialised technique or specialised equipment would be required for catheterisation. In the opinion of the witness, the pursuer was unfortunate to

develop BCG osis after his BCG administration, but there was no clear evidence to suggest that the catheterisation process was negligent and no clear evidence that catheterisation caused urethral trauma. The description of the process on 13 April 2016, could not be considered traumatic.

[26] Mr Barrett said that if there was no blood in the urine that drained after the initial catheterisation and no blood on the catheter when removed then those were positive signs, which indicated no trauma had occurred. Blood in the urine at the time of voiding the instillation was a known side effect following BCG treatment. He also said that the presence of stricture was not a contra indication to proceeding with BCG therapy and neither was resistance. Generally, a slight resistance could be overcome with a little bit of extra "gentle pressure". If the practitioner felt that the pressure might be too much then that is when he or she would seek alternative means. You would not force a catheter. It came down to an element of judgement based on experience. An experienced urology nurse would be expected to be able to pass the catheter through the urethra despite the presence of a slight stricture.

[27] In giving his opinion Mr Barrett had regard to the European Association of Urology Nurses (EAUN) Guidelines (2015) which indicate that a history of traumatic catheterisation can be a contra indication to BCG treatment but this can be dealt with by using extra care and there was no reason why the therapy should not have been administered on 13 April 2016. He disagreed with Nurse Dickinson's opinion that Nurse Gent-White should not have commenced the treatment on 13 April 2016. The cystoscopy in March 2016, following the induction treatment had involved passing a cystoscope far larger in diameter than the 12 Fg catheter used by Nurse Gent-White. Had there been any concern following the cystoscopy in March 2016, then it should have been raised by Mr Hendry. It was not. In his opinion,

Nurse Gent-White was not under a duty in the circumstances to seek Dr Das's opinion before commencing catheterisation on 13 April 2016, or during it. She was an experienced practitioner in her own right and it was reasonable for her to continue. Further, she was not in his view under a duty to refer the pursuer to an infection control unit. He explained that BCG osis is difficult to diagnose.

Amir Kaisary

[28] Mr Kaisary spoke to his report. He is a retired Consultant Urological Surgeon. He retired over 10 years ago. He has considerable experience in this field. He was instrumental in introducing BCG therapy into urological practice in the UK in the 1970s.

41. His evidence was that on initiation of booster BCG immunotherapy Nurse Gent-White did not observe the BCG Intervestical and Circulation Guidelines. It was contra indicated to proceed to intervesical BCG instillation in cases of difficult or traumatic instrumentation and/or bleeding. It was recommended to postpone giving intervesical BCG instillation until the bleeding stops. If a case of acknowledged difficult catheterisation it was encountered during the BCG six week course it would have been more appropriate to choose a catheter that could have negotiated previous difficulties such a Tiemann catheter, a Coude tipped catheter which was angled upward at the tip to assist in negotiating the upper bend in the male urethra and urethral stricture present. Such a catheter was utilised earlier where difficulties occurred. Also, Dr Das should have been called upon to assist as previously done during the induction course. On 13 April 2016, at 11:30am the pursuer complained of feeling cold, shivering, shaking and nauseas. Mr Kaisary was of the opinion that Dr Das failed to interpret the symptoms, which should have raised the strong possibility of septicaemia and urgent intervention applied. His comments and approach to

the pursuer, who was desperately unwell, fell below expected reasonable care. Such a specific treatment and procedure would not have been expected to be dealt with by a general practitioner to diagnose, interpret or address in the community setting. The pursuer would have needed systemic broad-spectrum antibiotic therapy, not paracetamol, in an isolation hospital facility under observation. The pursuer should have been read "the Riot Act". The event should have been notified urgently to Mr Hendry who oversaw the pursuer's care. The details of the episode were relayed to the general practitioner by a telephone call, but it was not clear if he was able to grasp the difficulties encountered with such a specialised procedure. Management of the patient in the community would have been impossible. Where the patient becomes septic, has a fever over 39.5C or a persistent temperature of over 38.5C for more than 24 hours, BCG osis can be suspected.

[29] Mr Kaisary indicated that BCG intervesical treatment is associated with variable mild side effects, which can be treated effectively in almost all cases. These were probably explained to the pursuer by Mr Hendry. Severe complications are rarely encountered and in only less than 5% of patients. However, a disseminated infection can occur, although rarely, leading to severe life threatening sepsis. BCG osis correlated with dramatic catheterisation or instillations given earlier after transurethral resection. Direct access of the bacteria to vascular circulation provokes disseminated BCG infection. Thus, he was of the view, it was a contra indication to proceed to BCG instillation following dramatic catheterisation and haematuria. He said that but for the instillation of BCG on 13 April 2016, when it was contra indicated, the pursuer would not have suffered disseminated BCG septicaemia and widespread defects.

[30] In cross-examination, it was put to Mr Kaisary that his opinion proceeded on the basis that there was traumatic catheterisation prior to BCG instillation on 13 April 2016. He

said in reply that that was a day when all the symptoms appeared and that it was quite likely there was a bit of bleeding after the stricture was dilated. He said that he could not prove it but that he could not ignore it. In response to the evidence that there was no blood in the urine that drained on catheterisation before the BCG instillation and that there was no blood on the catheter on its removal, he said that the fluid might have washed a bit of blood ahead of hit so one could not say for sure. He referred to the fact that there was blood noted when the pursuer voided urine, which he acknowledged however, is a known side effect of the treatment. Haematuria could occur in nearly 40% of patients and that it was a known side effect after BCG therapy. He accepted that the choice of catheter was a matter of clinical judgement. He acknowledged that the catheters used by Dr Das on the earlier occasions when he had been asked to assist involved resistance at prostate level and that those catheters were designed for navigating the prostate or prostatic urethra. He accepted that the EAUN Guidelines indicated that one should use the smallest size of catheter.

Professor Samuel McLinton

[31] Professor McLinton spoke to his reports and subject to certain corrections; he adopted them in his evidence. He is a retired Consultant Urological Surgeon having retired from clinical practice in 2017. He practiced as a Consultant at Aberdeen Royal Infirmary between 1993 to 2017 and had extensive experience in intervesical BCG therapy explaining that he had treated hundreds of patients. He would not carry out the treatment himself. That was done by trained nurse specialists. In his first report dated 4 September 2019, he referred to Dr Das as an associate specialist in urology and that on being informed he was in fact a general surgeon he indicated that he was not comfortable giving an opinion on the normal and standard practice for such a doctor working in a rural general hospital. He

expected the standard to be expected would be lower than a urologist in dealing with such matters. On the second page of his report, he acknowledged that he had incorrectly stated that on 13 April 2016, the catheter had been removed after two hours and bleeding noted on removal. He acknowledged that that was clearly incorrect. The report should have stated that after two hours the pursuer voided his bladder and had some bleeding at that stage. Having considered those corrections his opinion remained unaltered.

[32] In relation to traumatic catheterisation, the professor indicted that he did not think there was a definition but in his view, it is where there is pain and usually bleeding at the time of catheterisation. Bleeding would usually be seen around the catheter or on its tip. Depending on where the trauma occurred he would expect to see blood in the urine that drained when the catheter was inserted or at the tip of the penis. If there is no blood in the urine that drains initially and no blood on the tip of the catheter when removed then there is no sign of traumatic catheterisation. He did not agree that to move a catheter past a restriction when resistance was met was indicative of a traumatic catheterisation. It was quite common to meet resistance when putting in a catheter. The presence of a stricture in itself does not mean that you should not proceed with a catheterisation. If there is slight resistance but the catheter passes with ease beyond that point and there is no pain and no bleeding, he would assume that there was no trauma. It was quite common for there to be blood in the urine on voiding after BCG therapy and this was well reported in the literature. The reason is that BCG therapy causes inflammation in the bladder and that can lead to bleeding. It is not necessarily a sign of trauma. In his experience, penile urethral injury is uncommon because the penile urethra is quite a mobile area, which is hard to penetrate or damage. In his experience, most trauma would occur at the bladder neck/prostate level.

[33] In relation to strictures, he said that he would expect a urology nurse specialist to be able to catheterise a patient with a mild stricture. A mild stricture in the mid urethra would not mean that they should not proceed with catheterisation.

[34] In relation to the BCG treatment of the pursuer, Professor McLinton indicated, that catheterisation in the induction BCG treatment was not straightforward and required the assistance of Dr Das on two occasions. In his view Nurse Gent-White, an experience nurse dealt with these difficulties in an appropriate way by seeking help. When the pursuer attended in April 2016 for the first of the booster instillations, there was no evidence that there was any great difficulty in passing the catheter. Given the previous history with the pursuer there was no reason why Nurse Gent-White should not have given the BCG booster on 13 April 2016. At the time of the cystoscopy by Mr Hendry on 4 March 2016, there was no comment in the operative notes about any problem with the urethra but further biopsies were taken from the prostatic urethra at the time of that intervention. Sepsis and BCG osis related to BCG instillations is rare and Nurse Gent-White did seek an opinion from Dr Das at the time who apparently felt this was one of the more common reactions to BCG rather than anything more serious. Nurse Gent-White did contact the patient on a number of occasions thereafter and suggested he seek help from his GP. His eventual diagnosis of BCG osis was subsequently treated. Professor McLinton indicated that the complication is rare and although on the balance of probabilities, it is likely to have started when he was catheterised on 13 April 2016, it may have happened on any one of a number of occasions prior to that. It is not uncommon for there to be a delay between systemic BCG infection and the onset of symptoms.

[35] In his second report dated 21 August 2020, Professor McLinton confirms that the pursuer eventually had to have his bladder removed there being no evidence of a residual

tumour indicating a good response to his BCG treatments. There were complications following the bladder removal unrelated to the BCG treatment.

[36] Responding to Mr Kaisary's opinion, he agreed in principle having regard to the EAUN Guidelines that it is contra indicated to proceed with intervesical BCG therapy in cases of traumatic catheterisation. In relation to difficult catheterisation, not a term listed as a contra indication in the guidelines, this was subjective. It would be a matter of clinical judgement by whoever is doing the catheterisation. There was nothing in the pursuer's medical or nursing notes that would suggest that the pursuer had pain or bleeding at the time of the catheterisation on 13 April 2016 and therefore in his opinion no evidence of trauma.

[37] Professor McLinton disagreed with Mr Kaisary's view that it would have been more appropriate for Nurse Gent-White to use a Tiemann or Coude tipped catheter. He reasoned that during the six week induction course on the two occasions when she encountered difficulties this was at the bladder neck (prostate level). His view was that it was perfectly acceptable for her to use a smaller catheter as she did. In relation to Mr Kaisary's criticisms of Dr Das he was not comfortable providing an opinion on Dr Das's practice. Apart from his reluctance to opine on the normal and standard practice to be expected of a mid-level general surgeon he did not have any knowledge of how many cases of BCG instillation Dr Das had been involved in or what his experience was of complications arising from BCG instillations. He did not agree with the proposition that the pursuer's symptoms on 13 April 2016 would immediately raise a strong possibility of septicaemia. It might be one of many possibilities but, given the pursuer's normal observations, it would not be a strong thought in his mind that the pursuer had septicaemia. He explained that BCG osis is very rare and in his career, he had only seen two cases. The first one was picked up some six weeks after

treatment and the second was picked up around two to three weeks after in the middle of the patient's induction course. In both cases, there was no obvious cause or explanation as to why the complication arose. Professor McLinton was challenged on his conclusion because Nurse Gent-White did not call for assistance on 13 April 2016, that that was evidence that the catheterisation was not difficult. He said his assumption was based on her having called assistance on two previous occasions and that as an experienced nurse she was aware when to call for help and when there was a problem passing a catheter. On both occasions when she did call for help, resistance was at prostate level whereas on this occasion slight resistance was met at mid urethra. He explained that quite often when putting the catheter in resistance could be felt at the penile urethra (the mid urethra would be within that) but students are taught that if there is resistance at prostate to wait. Sometimes the catheter will pass and if not you stop and ask for help. If obstruction was met at mid urethra, it is often the case that with more lubrication or stretching the catheter will pass. However, if you meet obstruction at prostate level you may to change the catheter to a stiffer kind of catheter or use an introducer. In general, you would use a soft catheter, which is less likely to cause trauma of any kind. However, if obstruction is met, you may have to use a stiffer catheter to get past that.

Mr David Hendry

[38] Mr Hendry is the pursuer's treating Consultant. He is employed by Greater Glasgow Health Board. He was appointed Consultant in 2003 and treatment of bladder cancer is one of his sub-specialities. He had no direct involvement or clinical input in the operations at Lorn & Islands District Hospital nor any responsibility with the oversight of their operations. He simply referred patients there for treatment. He had been the pursuer's

treating consultant since 2015 and the pursuer remained under his care. He carried out the surgical procedure (re-section, including cystoscopy and trans urethral resection of bladder tumour (TURBT) and biopsy) in November 2015. Following that procedure consideration was given to the pursuer's options for treatment. His case was discussed at a Multi-Disciplinary Team ("MDT") Meeting. There were two treatment options:

1. Radical cystectomy (bladder removal)
2. Treatment with intravesical BCG.

Although it was thought that the radical cystectomy was the best option for long-term cure, the pursuer was keen to avoid the surgery and opted for BCG therapy.

[39] It was Mr Hendry's standard practice to explain to a patient what was involved in that treatment and the associated side effects. Many patients experienced UTI symptoms, mild flu-like symptoms for two to three days with a small number of patients experiencing more severe symptoms namely systemic reactions, joint pain and arthritis. In a small number of patients' illness could be caused by absorption of BCG but this was very rare. Since he had started urology in 1995, he had not had one case of this happening until the pursuer experienced this. He explained that the treatment was delivered in Greater Glasgow Health Board by a urological nurse specialist and because the pursuer lived in Mull, he was referred to Nurse Gent-White in Oban for treatment as being the most convenient for him. He spoke of the initial referral following upon his letter to Nurse Gent-White of 20 November 2015 and following the induction treatment, he performed a cystoscopy in March 2016, following which he re-referred the pursuer to Nurse Gent-White for three booster treatments, as per his letter of 8 April 2016 to her. Under reference to the GP records, he confirmed that it was he who wished the patient on 15 April 2016 to have "Cipro", short for Ciprofloxacin, a broad-spectrum antibiotic used for treating UTIs which

also has some effect against BCG. He looked at the blood results of the pursuer available on the portal. The bloods were taken on 28 April and the results were available on 29 April 2016. The blood results showed infection and he contacted the pursuer advising him to come to Glasgow – the Queen Elizabeth University Hospital – for admission. The pursuer was admitted on 2 May 2016 and on 8 May 2016 a diagnosis of disseminated BCG infection was made. He was very unwell when admitted.

[40] In September 2016, when he re-biopsied his bladder, there was still some transitional cell carcinoma present. Although of a low grade and given the presence of a persistent tumour which is associated with a poor prognosis he discussed with the pursuer proceeding to a radical cystoscopy which subsequently occurred on 7 December 2016. The final pathology showed no residual tumour in his bladder and no evidence of any disease in is pelvic lymph node dissection. He indicated that there was a very good long-term prognosis. In relation to the assertion of the pursuer that the catheter had penetrated the urethra, he indicated that a catheter can pass through the wall of the urethra creating a false passage but that there was no evidence to suggest such a false passage or any urethral injury on subsequent cystoscopies. He would have expected to see scarring or other evidence of residual damage. He suggested that given the fairly recent re-sections of his prostatic urethra and bladder neck it was possible that the catheter pushing past this area may have caused some bleeding given that it could take up to 6 weeks for healing of the urethra and bladder. Systemic BCG osis was a recognised complication of BCG treatment that was very rare and it was the first case he had seen as a urologist. Had there been significant injury caused in the catheter procedure he would normally expect to see some residual damage.

[41] During his check cystoscopy in March 2016 prior to the booster treatment he would have used a size 21 Fg and then a 26 Fg to reset the tumours, you require to dilate the

urethra to assist in passing the cystoscopies. The catheters used for catheterisation were significantly smaller in diameter. At the check, cystoscopy there was a sub-meatal stenosis. This is the area immediately in from the tip of the penis and is not the same as a mid-urethra. A stenosis can sometimes make it difficult to pass a catheter. If it was something he was concerned about or thought it would cause a difficulty in delivering BCG treatment, he would have mentioned it in his referral letter of 8 April 2016.

[42] He explained that if the urine that was drained out of the bladder once the catheter was removed was clear it would be reasonable to proceed with BCG treatment but if there was blood in the urine (haematuria) that drains from the catheter after catheterisation you should not proceed with the instillation. There was no standard definition of traumatic catheterisation, but normally, if traumatic, there would be some blood visible. In the absence of blood it would be reasonable to conclude that there was no trauma.

[43] In relation to the pursuer's reported symptoms of 13 April 2016, he indicated that they sounded like rigors which is a relatively common feature following all intervesical treatments and is normally in response to a bacterial infection with a bacteraemia and in this situation this would be the most likely diagnosis. Symptoms of bacteraemia could develop within one to two hours. However, the precise mechanism by which BCG osis develops is not understood but usually takes between seven to ten days. An acute response within hours such as experienced by the pursuer on 13 April 2016, would normally be due to a bacterial UTI.

Professor Clifford Leen

[44] As indicated at the outset by Professor Leen's report (dated 9 August 2019) it was agreed between the parties to be the equivalent of his evidence in the case.

[45] At the time of his report, Professor Leen was a Consultant Physician in Infectious Diseases and Lead Clinician for Clinical Research in the Regional Infectious Diseases Unit in Edinburgh. He was also Honorary Professor in the School of Molecular Clinical Medicine at Edinburgh University. He has been involved with specialist training of doctors in infectious diseases. He has been on the Specialist Advisory Committee of the Joint Committee of Higher and Medical Training and now the Joint Royal Colleges of Physicians Training Board until 2016. Since November 2016, he had ceased in patient work and continued without patient clinical work and clinical research.

[46] The professor concluded in his report that the pursuer developed systemic BCG infection on the 13 April 2016, during intravesical BCG treatment and that this is a very rare complication of such treatment. Disseminated infection following BCG intravesical treatment is extremely rare and has been reported as occurring in 0.4 of patients, more recent estimates being that it occurs in about 1 out of 15,000 patients. He noted that the pursuer had completely recovered from his systemic BCG and observed that further BCG treatment is contra indicated. He went on to say:

> "Although not proven, breaches of urinary tract mucosa have been associated with systemic BCG infection in the past. However, where recent reported cases of systemic BCG infection have not been associated with traumatic bleeding".

[47] In relation to the pursuer's "losses" the professor indicates that the pursuer required six months of treatment and had some side effects including indigestion and difficulty sleeping but he had made a complete recovery from his systemic BCG infection. There was no record of the pursuer complaining of joint problems and there was no indication that this disseminated BCG would predispose him to an increased risk of arthritis in the future.

[48] Professor Leen was not a urologist.

Submissions

[49] Following the conclusion of evidence there was an adjournment to a later date for submissions with written submissions being lodged on behalf of each of the parties prior to the hearing.

[50] For the pursuer Mr Markie moved the court to sustain the pursuer's first and fourth pleas in law (merits and damages) and to pronounce decree in favour of the pursuer in the sum of £51,799.99 inclusive of interest to the date of the proof. He also made a motion for expenses, sanction of junior counsel and certification of Doctor Kaisary and Nurse Sally-Ann Dickinson as skilled witnesses.

[51] I was referred to the legal test in relation to the standard of care in medical negligence cases as stated in *Hunter* v *Hanley* 1955 SC200. He referred to the evidence of the witnesses. On the issue of liability, it was submitted that Nurse Vent-White was negligent in performing the catheterisation of the pursuer on 13 April 2016; in failing to terminate the BCG instillation; in failing to call for Dr Das to assist with catheterisation; and in failing to identify the seriousness of the event, which had occurred. In relation to Dr Das, it was submitted that he was negligent in 1. Failing to advise the pursuer of the seriousness of the event, which had occurred, and 2. In failing to refer the pursuer to hospital.

[52] It was submitted that the defender did not offer to prove that the pursuer's refusal to be admitted to hospital following discussion with Dr Das constituted a *novus actus interveniens* or that it went to the issue of causation at all. It was submitted that the evidence established that had the pursuer been advised either by Dr Das or Nurse Gent-White that he may have been exposed to BCG and therefore was at risk of developing a potentially life threatening condition, he would have followed the advice (to stay in hospital). Dr Das

candidly admitted that he did not advise the pursuer of the life threatening nature of the potential risks to which he had been exposed.

[53] As to the contested issues of primary effect, it was submitted that the evidence of the pursuer was to be preferred. It should be found that on 13 April 2016, Nurse Vent-White encountered resistance in catheterisation of the pursuer. Despite that resistance, Nurse Gent-White continued with the catheterisation. As a result, the pursuer suffered a urethral injury. He was exposed to the BCG vaccine on 13 April 2016 and subsequently developed BCG osis.

[54] It was submitted that the evidence of Nurse Dickinson and Mr Kaisary established that the usual and normal practice in the event that resistance was felt was that the attempt at catheterisation should be terminated. Their evidence established that Nurse Gent-White's failure to cease the attempt was negligent. In any event, the evidence established that the pursuer had a history of difficult catheterisation prior to 13 April 2016, and that Nurse Gent-White had failed to take any steps in accordance with the guidelines to reduce the risk of injury. She did not take extra care with the catheterisation. She did not use extra lubricant. She did not select an alternative catheter. She did not call for a more experienced clinician (Dr Das). To fail to do so was negligent.

[55] The pursuer's case was that he was not advised to remain in hospital, which is in conflict with the evidence of Dr Das and Nurse Gent-White. The nursing record made no mention of a request to remain in hospital overnight. In the event that the court concluded that, the pursuer was advised to remain in hospital overnight but not advised of the potential seriousness of his condition it was submitted that that would amount to negligence on the part of the defender's employees. Mr Kaisary was very clear on the obligation on Dr Das to inform the pursuer of the potential seriousness of the symptoms he was experiencing.

It was submitted that Dr Das was under a duty to advise the pursuer of the risk of developing BCG osis or BCG sepsis following the symptoms experienced on 13 April 2016. The fact that Dr Das was not a urologist was irrelevant as he knew of the risks of BCG infection but elected not to inform the pursuer. Mr Kaisary's evidence supported that view. The failure of Dr Das and Nurse Gent-White to recognise the potential seriousness of the situation informed their approach as to whether this was a matter, which should have required a referral to an infectious disease control unit.

[56] It was submitted that the evidence of the defenders skilled witnesses should be rejected. Nurse Barrett and Professor McLinton appeared to approach the issue by accepting at face value the actions of Nurse Gent-White that is to say the underlying rationale for their conclusion was that she was not negligent and to point to previous incidents where she had called Dr Das as evidence of her understanding of when to do so. On the contrary, the fact that she did call for Dr Das on previous occasions when there was resistance and did not on 13 April 2016, tended to point to the conclusion that she was negligent not to do so.

[57] It was submitted that Mr Hendry was a witness to fact and not a skilled witness for the purpose of the case and so I was invited to place no weight on his evidence of opinion (although not objected to). I was referred to *Kennedy* v *Cordia (Services) LLP* [2016] 1WLR 597.

[58] In relation to causation it was submitted under reference to the evidence of Professor McLinton and Professor Leen that the uncontested evidence was that as a result of the treatment on 13 April 2016, the pursuer went on to develop BCG osis. But for the negligence of the defenders employees the pursuer would not have developed the condition. Further, had the pursuer been properly advised of the risks, he would have followed the advice to be admitted to hospital. The evidence established that in the event of Nurse Gent-White

terminating the treatment on 13 April 2016, as she was required to do the pursuer would not have developed BCG osis as he later did. In the event that she called the assistance of Dr Das once resistance was encountered the pursuer would have been catheterised by Dr Das and it is more likely than not that the pursuer would not have suffered a urethral injury or mucosal tare and would not have gone on to develop BCG osis. In the event that Nurse Gent-White had deployed the mitigation strategies identified in the Guidelines the pursuer would not have suffered a urethral injury or mucosal tare and would not have gone on to develop BCG osis. In the event that the pursuer had been advised by either or both of Dr Das or Nurse Gent-White of the potential seriousness of the complication he would have agreed to hospital admission and in that event would have been prescribed either ciprofloxacin or broad spectrum antibiotics and would not have gone on to develop BCG osis as he did.

[59] In relation to quantum it was submitted on behalf of the pursuer that the following factors are relevant in the assessment of damages:

1. At the time, the pursuer developed BCG osis he was undergoing treatment for bladder cancer and was therefore already debilitated.
2. The treatment of the pursuer's bladder cancer was delayed.
3. The pursuer was exposed to a life threatening condition.
4. The pursuer required hospital admission and the provision of medication.
5. BCG motivates a strong immune reaction and therefore immunologically induced diseases, symptoms can be expected, and so the pursuer remains at risk.
6. The pursuer would not have needed to receive the anti-tuberculosis triple medication.

No authority was referred to in relation to quantum but it was submitted that solatum should be assessed at £35,000 all of which was attributable to the past with interest thereon 8% per annum for 13 April 2016, to date amounting to £16,799.99. The total award would therefore be £51,799.99.

[60] On behalf of the defender Ms Bennett moved the court to sustain the defenders third and fourth pleas in law (the merits) and assoilzie the defender from the craves of the initial writ.

[61] She referred to the legal test in *Hunter v Hanley sup cit*, which both sides agreed was the relevant test in relation to the alleged negligence of both Nurse Gent-White and Dr Das. Further, to succeed the pursuer must establish as a matter of fact a causal connection between any proved negligent act or omission and injury sustained. The onus of proof in relation to liability and causation was with the pursuer. She referred to the parties averments on record. The pursuer offered to prove that Nurse Gent-White was under duty to:

1. Cease the BCG therapy following traumatic catheterisation on 13 April 2016.
2. Follow the Urological Health Guidelines.
3. Recognise the seriousness of the event, which occurred in relation to catheterisation and subsequent BCG booster therapy and to convey the seriousness of that to the pursuer.
4. To select a Tiemann or Coude-tipped catheter.
5. Seek assistance of Dr Das in the insertion of the catheter.
6. Refer the pursuer to an infections control unit and notify Mr Hendry.

[62] In relation to Dr Das, the pursuer offered to prove that he was under a duty to:

1. Refer the pursuer to hospital for a valuation and specialist infectious disease control input.
2. To advise the pursuer of the seriousness of the event.
3. To refer the pursuer immediately to the infection control unit.

[63] As was apparent from the defender's pleadings there was a large measure of agreement as to the factual background of the pursuer's treatment. The defenders position was that Nurse Gent-White and Dr Das fulfilled all duties incumbent upon them.

[64] Reference was made to the evidence of each of the witnesses. In relation to the pursuer, it was submitted that he was neither credible nor reliable as a witness. His evidence as to the catheterisation on 13 April 2016 was exaggerated and inconsistent with the averments he offered to prove on record. Reference was made to the differences between his oral evidence and the terms of his complaint in July 2016. There was no mention of the catheterisation process being traumatic or causing pain at the time of his complaint. It was submitted that both Nurse Gent-White and Dr Das presented as credible and reliable witnesses and that their evidence ought to be accepted. In respect of the pursuer's nursing expert Sally-Ann Dickinson it was submitted that the court could place little if any reliance on her evidence under reference to *Kennedy* v *Codia (Services) LLP sup cit*. She had significant experience in providing expert witness evidence. However, her listed fields of experience excluded urology and her experience in relation to that field was comparatively limited. In relation to the defender's nursing expert, Anthony Barrett, it was submitted that he presented a cogent and reasoned opinion. He had regard to the EAUN Guidelines relied on by the pursuer. He had regard to his considerable experience, knowledge and understanding of the standard expected of an ordinarily competent urology nurse specialist. In relation to Mr Kaisary, it was submitted that while he had considerable

knowledge of BCG treatment and considerable experience as a consultant urological surgeon, the conclusions in his report did not stand up to scrutiny. As regards Professor McLinton it was submitted that he provided a cogent and reasoned opinion which, in contrast, stood up to scrutiny. As regards Mr Hendry, it was submitted that he too presented as both a credible and reliable witness. It was made clear in oral submissions that Mr Hendry was not led as an expert for the purpose of providing opinion evidence, and his evidence as to his findings in the cystoscopies performed subsequent to the BCG treatment should be taken into account and accepted.

[65] In relation to breach of duty, it was submitted that he pursuer had failed to prove that the conduct of either Nurse Vent-White or Dr Das fell below the acceptable standard under reference to the three stage tests for medical negligence in *Hunter* v *Hanley*. In particular, the pursuer had failed to prove that Nurse Vent-White departed from the normal practice and that no ordinarily competent urology nurse exercising ordinary skill and care would have so departed. He had also failed to prove that Dr Das departed from normal practice and that no ordinarily competent middle grade general surgeon exercising ordinary skill would have so departed.

[66] In relation to causation, it was submitted that the pursuer's case failed. The pursuer's reaction to BCG treatment on 13 April 2016 was a known but rare complication. Even if the catheterisation on 13 April 2016 was traumatic, development of systemic BCG infection was not necessarily caused by traumatic catheterisation and reference was made to the evidence of Professor Leen. Further, as Mr Hendry explained, following bladder re-section/surgery healing of the bladder lining can take up to six weeks. The EAUN Guidelines state that it is an absolute contra indication to give BCG therapy within two weeks of TURBT. In any event, it was submitted that the pursuer's reaction on 13 April 2016

was probably a bacteraemia, not the start of BCG osis. Reference was made to the evidence of Mr Hendry in this regard and also the evidence of Professor McLinton.

[67] It was submitted that the pursuer had offered to prove that, but for the alleged breach of duty to recognise and advise him of the seriousness of the event, he would have been commenced on intravenous antibiotics and on the balance of probabilities the diagnosis of disseminated BCG infection would have been made. It was clear from the EAUN Guidelines, NHS Highland protocol, Patient Information Leaflet and witness evidence that only when the patient has a fever of over 39.5 degrees or more for more than 48 hours should BCG osis be suspected. Had the patient remained in hospital on the evidence of Dr Das he would have been monitored under the Sepsis 6 protocol. Whether the pursuer would have had a persistent fever beyond 48 hours is not known. He did not have a fever at the time he was assessed by Dr Das. Mr Hendry explained that systemic BCG infection is not well understood but symptoms usually present around seven to ten days after treatment. Professor McLinton gave evidence about his two cases of BCG osis both of which were picked up some weeks after treatment. A diagnosis of likely BCG infection was made six days after the pursuer's admission to hospital in Glasgow. The pursuer's averments on what would have happened but for the alleged failure on the part of Nurse Gent-White and Dr Das, were speculative. Further, Mr Hendry, having been made aware of the pursuer's symptoms recommended a prescription of oral (not intravenous) antibiotic in the form of ciprofloxacin on 15 April 2016. He did not advise on admission to hospital nor referral to the Infectious Diseases Unit. The pursuer gave no explanation as to why he did not see his GP until 28 April 2016, despite being advised to do so on leaving hospital and on several occasions thereafter. It was speculative to suggest that, had the pursuer commenced oral ciprofloxacin earlier, then that would have made a difference to the outcome. It was

therefore submitted that there was insufficient evidence to allow the court to find that the pursuer's diagnosis would on the balance of probabilities have been identified earlier and that that would have made a material difference to the outcome.

[68] In relation to quantum of damages, it was submitted that this could be assessed at £5,000 plus interest. The pursuer's reaction to BCG therapy was picked up within a month of treatment and he received appropriate treatment thereafter. He was fully recovered within six months. The diagnosis of BCG osis had no bearing on the outcome for the pursuer in so far as his bladder cancer is concerned. It was not disputed that a radical cystectomy was always likely to be required.

Discussion

[69] There is no issue as to the legal test that must be applied in this case to establish liability. That is the test set out in *Hunter* v *Hanley sup cit* where Lord President (Clyde) said at page 206:

> "To establish liability by a doctor where deviation from the normal practice is alleged, three facts require to be established. First of all it must be proved that there is a usual and normal practice; secondly it must be proved that the defender has not adopted that practice; and thirdly (and this is of crucial importance) it must be established that the course the doctor adopted is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care. There is clearly a heavy onus on the pursuer to establish these three facts, and without all three his case will fail".

[70] It was accepted on both sides that this was the test to be applied when judging the actings of both Nurse Gent-White, a urology nurse specialist, and Dr Das a middle grade general surgeon. It is clear that nursing staff, as well as medical practitioners owe a duty of care to patients in their care and the principles relating to liability of doctors applies equally to nurses. The nurse must thus attain the standard of competence and skill to be expected

from a person holding their post. The more skilled the job undertaken by the nurse, the higher the standard of care expected. (*Clerk and Lindsell on Torts* 23rd Ed. at paragraph 9-98).

[71] Further, liability to make damages depends on it being proved that negligence, if established, caused the damage in issue. In other words, the pursuer must establish on the balance of probabilities that a breach of duty caused him injury. It depends on the facts of each case whether the breach leads to a legitimate inference that the injury resulted. The onus is on the pursuer to prove both the breach of duty and the causal connection between any breach and any injury.

[72] In relation to the witnesses, I found the pursuer to be generally credible in the sense that he was doing his best to give a true recollection of events, but perhaps understandably, given the passage of time, his recollection was not reliable on all points, and in particular, as we have seen, in relation to the events of 13 April 2016. I found both Nurse Gent-White and Dr Das to be both credible and reliable. As for the expert witnesses, it will become apparent that, on certain important matters, I have preferred the opinion evidence of Professor McLinton to that of Mr Kaisary, and that of Mr Barrett to that of Ms Dickinson as being more consistent and persuasive.

[73] In relation to Mr Hendry, the parties were at odds in relation to the way in which his evidence ought to be treated under reference to *Kennedy v Cordia (Services) LLP, sup cit.* Mr Hendry was in my view a skilled witness in the sense that he possessed relevant knowledge and experience to give factual evidence, not based exclusively on personal observation or sensation (paras. 40 to 50 of *Kennedy v Cordia*). He was not called as, and I did not regard him as, a witness called upon to give opinion evidence. I found his evidence as to fact to be both credible and reliable.

[74] In relation to the question of breach of duty, it is convenient to deal with this aspect under reference to the pursuer's case on record, which, when drawn together, comes under the following heads, although it is apparent that there is some overlap between them.

Nurse Gent-White

Duty to cease BCG booster therapy following traumatic catheterisation

[75] As observed in the submissions of the defender this case is predicated on proving that traumatic catheterisation occurred on 13 April 2016 prior to the installation of the BCG solution. Initially, the pursuer gave evidence that he immediately suffered pain during the process of the catheter being inserted. However, as also noted, and under reference to his complaints form submitted to the defender on 6 July 2016, he accepted that in fact he only began to feel unwell around one hour after the catheterisation. The pain, shock, shaking and nausea did not come on during the catheter being inserted. There was no pain at this time. Further, when the bladder was drained following insertion of the catheter there was no evidence that there was blood in the urine. On removal of the catheter, there is no evidence that there was blood on the tip of the catheter. That being so, there is no evidence of trauma and I accept the evidence of Anthony Barrett and Professor McLinton in this regard. The evidence of Sally-Ann Dickinson that there was blood in the urine at the time of voiding the bladder ignored one common, well recognised and documented side effect of BCG therapy: haematuria or blood in the urine after treatment. Mr Kaisary seemed to have found on the fact the 13 April 2016 was the day when all the symptoms appeared and indicated it was quite likely that there was a bit of bleeding after the stricture was dilated. His analysis proceeded on the basis that the dilation of the stricture was likely to cause bleeding. He could not prove that but said that he could not ignore that. In response to the evidence that

there was no blood in the urine that drained on catheterisation before BCG instillation and that, there was no blood on the catheter on its removal he said that the fluid (presumably urine) might have washed a bit of blood ahead of it so you cannot say for sure. He indicated that it could just be a scratch or a pull and it could be a microscopic haematuria, which you would not see with the naked eye. On pushed on the issue he sought to rely on the fact that there was bleeding noted when the pursuer voided urine, again disregarding the acknowledgement in his own report referring to the known side effect of BCG therapy in particular haematuria in 40% of patients. He accepted that this was a known side effect.

[76] There is also the evidence of Mr Hendry, factual evidence, that on subsequent cystoscopies there was no evidence of urethral injury or a false passage. While healing may have occurred by the time of his examinations there was normally to be expected some sign of damage or scarring.

[77] It is true that on 13 April 2016, Nurse Gent-White met some resistance when inserting the catheter but, there is no evidence to suggest, or at least no convincing evidence, that the fact of resistance indicated trauma.

Duty to follow the Urological Health Care Guidelines

[78] This is clearly related to the previous head. The Guidelines referred to in evidence were the "*Evidence-Based Guidelines for Best Practice in Urological Health Care*" in relation to "*Intravesical instillation with…[BCG] in non-muscle invasive bladder cancer*" published by the European Association of Urology Nurses (EAUN) in 2015. It is noteworthy that in the section dealing with "*Common problems identified in assessment*" under the head "*History of traumatic/difficult catheterisation causing bleeding*" the nursing solution is stated as "*Catheterise with extra care, use more lubricant than usual, consider alternative, or more experienced personnel*".

In my view, it is not established on the evidence that there was previous traumatic catheterisation. If it is suggested, as it was at one point by Ms Dickinson, that the catheterisation should not have proceeded on 13 April 2016, that is not a case which is made on record. In any event, if there was traumatic catheterisation in the induction treatments, this would not preclude catheterisation on 13 April 2016 having regard to the said guidelines, provided "extra care" was taken. I accept the evidence of Anthony Barrett in this respect which is clearly supported by the guidelines. I also accept the evidence of Nurse Gent-White that she took extra care on this occasion and indeed used adequate lubricant. In fact, it would appear on the evidence that she used at least twice the amount of lubricant that is normally required. She also used a small size of catheter as recommended in the guidelines. Further, I find it highly unlikely that Mr Hendry would have referred the pursuer back for booster treatment, following a further cystoscopy, if he thought that catheterisation should not proceed. He mentioned the presence of a stricture, but that was clearly not a bar.

[79] As regards the stricture, again this did not preclude proceeding with the catheterisation procedure. At the end of the day, I think it was accepted all round that it is ultimately a matter for the clinical judgement of the practitioner. Nor do I accept the proposition that because Nurse Gent-White asked for the assistance of Dr Das on two previous occasions during the induction treatment indicated that she was negligent in not asking for his assistance on 13 April 2016, when resistance was encountered. Rather, I consider that it is evident that she knew very well the limit to which she could go given her expertise and years of experience and on this occasion came to the judgement, quite legitimately, that she could pass the catheter. The catheter was passed. The bladder was emptied of urine and the BCG solution was instilled. There is absolutely no evidence

whatsoever that a false passage was created in the urethra. In coming to those conclusions, I have accepted the opinion evidence of Professor McLinton and Anthony Barrett on the issue and the evidence of Mr Hendry on the factual aspect.

[80] I am unable to conclude that Nurse Gent-White ought not to have either proceeded with, or continued with, the catheterisation on 13 April 2016, or that she failed to follow the said guidelines in doing what she did.

Duty to recognise the seriousness of the event which occurred, and to convey the seriousness to the pursuer

[81] I am unable to conclude that the seriousness of "the event", in the sense that it represented a possibility of BCG osis, ought to have been apparent to a urology nurse specialist. As far as Nurse Gent-White was concerned, I accept that she could not know at the stage the pursuer was displaying his symptoms that he would go on to develop BCG osis or even be at significant risk of that. Diagnosis would depend upon there being a high fever. That was the evidence of Mr Kaisary. The pursuer's observations were normal. In relation to the symptoms displayed by the pursuer, it seems perfectly reasonable for someone in the position of Nurse Gent-White to have regarded them as a no more than a common side effect of the BCG treatment. In this respect, I accept the evidence of Mr Barrett and Professor McLinton. It was perfectly reasonable, as is borne out by their evidence, to regard the "rigors" as a recognised side effect of BCG treatment. Systemic infection, as has been recorded in my findings in fact, is extremely rare. Further, it is clear that when Nurse Gent-White noticed the symptoms, she appropriately escalated the matter to Dr Das.

[82] Of course, Nurse Gent-White's advice to the pursuer, along with Dr Das, was that he should stay in hospital for observation. In the circumstances, it seems to me that that she complied with her responsibilities as a urology nurse specialist.

Duty in the circumstances of the pursuer's previous difficult catheterisations and prednisolone therapy to select a Tiemann catheter or a Coude-Tip catheter on 13 April 2016

[83] The pursuer's previous catheterisations which might be described as "difficult" and when Nurse Gent-White called for Dr Das's assistance, involved resistance at the prostate (prostatic urethra). The Tiemann and Coude-Tip catheters are designed to navigate the prostatic urethra. On 13 April 2016, Nurse Gent-White encountered slight resistance at the mid-urethra but was able to pass the catheter. No resistance was in fact encountered at prostate level. It was entirely reasonable in these circumstances and in accordance with normal practice for Nurse Gent-White to select, a size 12 Fg, catheter and I accept the evidence of Mr Barrett and Professor McLinton in this respect. The issue of prednisolone was not something which featured in the evidence to any significant extent, and I do not understand any submission to have been made in relation to that.

Duty to seek the assistance of Dr Das to catheterise the pursuer as had previously been done

[84] As indicated above, on 13 April 2016, there was no resistance at prostate level and I accept the opinion of Mr Barrett and Professor McLinton that an experienced urology nurse would be expected to have the skill to pass a catheter in the presence of a mild stricture. The decision as to whether to seek his assistance was a matter for her clinical judgement given

her expertise and experience. She would be governed by her "feel" of the degree of resistance. I do not accept the evidence of Ms Dickinson that she should not have proceeded. In coming to this conclusion, I have concluded that Mr Barrett was more qualified to provide an opinion on this given his greater experience in urology.

Duty to refer the pursuer to Infections Control Unit and notify Mr Hendry

[85] In the circumstances of this case, I have been unable to conclude that Nurse Gent-White had any such duty and such a conclusion follows naturally from my conclusions thus far on her justified impression of the pursuer's symptoms. In a circumstances such as this, where a doctor was also involved, I consider that it would be for the doctor, rather than the nurse to make any reference to hospital or a specialist unit within the hospital if he or she felt it was appropriate (*Clerk & Lindsell on Torts, sup cit*). Of course it is tolerably clear on the evidence that Nurse Gent-White was in contact with Mr Hendry by 15 April 2016 at the latest when he prescribed a broad spectrum antibiotic, not hospitalisation in a specialist unit.

Dr Das

Duty to: 1. Refer the pursuer to hospital for evaluation and specialised infectious disease input and 2. To advise the pursuer of the seriousness of the event

[86] In the circumstances of this case, I am unable to conclude that Dr Das had a duty to refer the pursuer to hospital for specialist evaluation. The difficulty in this case is that we do not have an expert opinion on the duties of a middle grade general surgeon in this situation. Without that, it is difficult to come to any clear conclusion as to the extent of his duties. I am not persuaded that Mr Kaisary is able to provide such an opinion and indeed Professor McLinton felt uncomfortable with the idea. However, the evidence appears to be that the

symptoms displayed by the pursuer approximately one hour after the instillation of the BCG solution were consistent with common side effects associated with the treatment. While Dr Das was aware in general terms of the risks of BCG osis, he was not a urologist, which seemed to come as a surprise to the parties. He was a middle grade general surgeon in a local hospital. While Mr Kaisary was of the view that BCG osis, while a remote possibility, ought to have been in the forefront of the mind of Dr Das, I am unable to come to that conclusion. While Dr Das had a knowledge of the potential for BCG osis, that was not derived from any experience in urology. He suspected, when he observed the pursuer's symptoms that he may have a UTI, commonly associated with catheter procedures. While not comfortable with giving an expert opinion on the duties of a general surgeon such as Dr Das, Professor McLinton confirmed that the doctor's impression at that stage would be a valid one. It is recognised that a UTI is a common side effect of BCG treatment with the associated "rigors". Given that the observations of the pursuer taken by Nurse Gent-White were normal, that it would be sufficient to prescribe paracetamol in the first instance was not in my view unreasonable. In any event, it appears from the evidence of Dr Das and Nurse Gent-White, which I accept, that the pursuer was indeed asked to remain in the hospital for observation. It is true that the medical notes do not record that in terms. However, they do record that the pursuer "insisted" on leaving the hospital and going home. The pursuer himself appeared to accept that he may have been asked to remain in the hospital. It appears that, given the events that transpired, he simply wanted to get out of the hospital, and that is, on one view, an understandable human reaction. Had the pursuer remained in hospital for observation, further consideration could have been given by medical staff to the need for further treatment and onward referral if necessary. Ultimately, it came to be the pursuer's position that he was not appraised of the seriousness of the situation. If he had

been, he would have stayed in hospital. Accordingly, to Mr Kaisary he should have been read the "Riot Act". That conclusion was based on the contention that "any doctor" would suspect septicaemia . I am not prepared to accept that. It is not consistent with the evidence of Professor McLinton, which I prefer, and the evidence accepted on all sides that his symptoms were consistent with a common side effect. In these circumstances, I am not prepared to hold on the evidence that Dr Das fell short in his treatment of the pursuer. A particular duty is said to have existed that Dr Das immediately refer the pursuer to hospital, specifically an infection control unit following his examination on 13 April 2016. For the reasons given, I am not prepared to hold that he had any such duty.

Conclusion on Breach of Duty

[87] My conclusion on the allegation of breach of duty is that the pursuer has failed to prove material facts sufficient to establish that either Nurse Gent-White or Dr Das were negligent. The pursuer has failed to prove that Nurse Gent-White departed from normal practice and that no ordinarily competent urology nurse exercising normal skill and care would have so departed. Similarly, the pursuer has failed to prove that Dr Das departed from the normal practice and that no ordinarily competent general surgeon exercising ordinary skill and care would have so departed.

Causation

[88] There can be little doubt, on the evidence, that the BCG osis developed after the treatment on 13 April 2016. Professor McLinton, in his report, stated if that:

> "His eventual diagnosis was BCG osis for which he was appropriately treated. This complication is rare and although on the balance of probabilities, is likely to have started when he was catheterised on 13 April 2016, it may have happened on any one

> of the number of occasions before that. It is not uncommon for there to be a delay between systemic BCG infection and the onset of symptoms".

[89] Professor Leen in his report indicated:

> "As discussed earlier, disruption of mucosal integrity from a recent urologic procedure or during the bladder treatment is strongly suspected but unproven as the pre-disclosing factor [in] the dissemination of BCG…He developed BCG infection on 13 April 2016 during treatment with further in intravesical BCG treatment. This is a very rare complication of BCG treatment…Although not proven, breaches of urinary tract mucosa have been associated with systemic BCG infection in the past. However, more recent reported cases of systemic BCG infection have not been associated with traumatic bleeding".

[90] The real question is of course whether the BCG osis can causally be connected with underlying negligence (if established). I am unable to conclude that this is so. While it may be reasonably inferred from the evidence that the BCG osis had its origins in the procedure undertaken on 13 April 2016, I cannot be satisfied as to the mechanism. It also has to be recalled that the pursuer had undergone earlier procedures involving re-sections and surgery to the bladder, which can, it is reasonable to assume, on the evidence, have made the pursuer vulnerable to injury on catheterisation.

[91] The picture is further obscured by the possibility, which cannot be ruled out on the evidence, that the symptoms displayed by the pursuer on 13 April 2016, were attributable to bacteraemia or a UTI.

[92] In the context of the alleged breach to recognise and advise the pursuer of the seriousness of the event and refer on to a specialist unit, it is clear on the evidence that the pursuer's observations were normal and that it is only when a patient has a fever that BCG osis can be suspected. The uncontroverted evidence of Mr Kaisary was that this is where the patient becomes septic, has a fever over 39.5C or a persistent temperature of over 38.5C for more than 24 hours. Had the pursuer remained in hospital as advised by Dr Das, he would have been monitored. Whether he would have developed a fever or persistent fever at that

time, or within say 24 or 48 hours, is not known. He did not have a fever at the time he was assessed by Dr Das. It seems clear on the evidence that systemic BCG infection is not well understood and symptoms appear some days or weeks after treatment. The diagnosis of BCG infection was made six days after the pursuer's admission to the Queen Elizabeth University Hospital. In other words, had the pursuer remained in hospital, or been referred to a specialist unit, it is not apparent what difference that would in fact have made to the eventual outcome. What is clear from the evidence is that Mr Hendry, having been made aware of the pursuer's symptoms recommended a prescription of an oral antibiotic on 15 April 2016. He did not advise on admission to hospital nor referral to an infectious diseases unit. Further, no explanation was given as to why the pursuer did not see his GP until 28 April 2016 despite being advised to do so on leaving hospital and on several occasions thereafter.

[93] So on the whole there is not sufficient evidence to enable me to conclude that any breach on the basis of the procedure carried out on 13 April 2016 or on the basis of failing to recognise the seriousness of the event or failing to refer the pursuer to hospital is in any way causally connected to the outcome for which the pursuer claims damages.

Damages

[94] If I am wrong in my conclusions on liability and causation I consider that damages in this case would appropriately be assessed at around £10,000, all of which would be attributable to the past and interest being applied thereto at one half of the judicial rate. After contracting BCG osis, he was fully recovered within six months.

Decision

[95] Given my conclusions, I will grant decree of absolvitor. I will reserve expenses in the meantime and appoint a hearing thereon on a date to be fixed.