OUTER HOUSE, COURT OF SESSION

2020 CSOH 53

A302/16

OPINION OF LADY CARMICHAEL

In the cause

ALAN MCNAB AND OTHERS

Pursuers

against

GREATER GLASGOW HEALTH BOARD

Defender

Pursuers: Clarke QC, R Macpherson; Digby Brown
Defenders: Doherty QC; CLO

28 May 2020

Introduction

[1] The pursuers are relatives of the late Alexandra McNab ("the deceased"), who sue variously as her executor dative and as individuals. They allege clinical negligence on the part of Ms Lizette Seaward, a consultant urological surgeon employed by the defenders. The proof related to negligence and some disputed aspects of causation. Quantum of damages was agreed between the parties.

[2] The following matters are not in dispute. The deceased died on 27 September 2013. She had developed multi-organ failure secondary to sepsis. The sepsis was caused by a

right rigid ureteroscopy carried out on 23 September 2013. Ms Seaward carried out that procedure.

[3] The deceased had a history of renal stone disease. In October 2011 she was admitted to Glasgow Royal Infirmary. She was found to have an obstructing stone. She suffered from urosepsis in the course of that episode. She was again admitted to Glasgow Royal Infirmary in April 2012. She underwent a right flexible ureteroscopy during that admission, and recovered without complications.

[4] She was seen at Glasgow Royal Infirmary on 18 July 2013 with right flank pain. She was treated with medication and discharged home on 24 July 2013, with arrangements for follow-up in the urology clinic two weeks later. She was reviewed on 5 August 2013 and placed on a list for a right ureteroscopy. An X-ray was taken on 5 August 2013 ("the August X-ray"). It is common ground that it did not show an obvious ureteric stone, whereas an X-ray taken on 18 July 2013 ("the July X-ray") did. The decision to list the deceased for a right ureteroscopy was taken by a Dr Henderson.

Summary of issues

[5] The pursuers allege that Ms Seaward failed to obtain the deceased's informed consent to the procedure. They plead that she had a duty to discuss fully with the deceased the options for treatment and the risk or benefits of those options. She had a duty to discuss "the heightened risk of urosepsis given the deceased's previous history of postoperative sepsis". They plead also that she had a duty to confirm the continued presence of a stone prior to submitting the deceased to the procedure. She had a duty to obtain further imaging, namely a KUB CT scan to confirm the presence and position of the stone before proceeding with the procedure. In the absence of that imaging she should have cancelled the procedure.

It is alleged, further, that Ms Seaward had a duty to obtain and check the deceased's urine cultures before proceeding.

[6] The pursuers' case is that if the risks associated with ureteroscopic surgery, and the risk of urosepsis, had been explained to the deceased, she would not have consented to the procedure. If the defenders' staff had instructed a CT scan of the kidneys, ureters and bladder ("KUB"), the procedure would have been delayed until the result was available. It would not have shown a stone, and the deceased would not have had the procedure.

[7] The defenders' case is that Ms Seaward did obtain the informed consent of the deceased. There was no increased risk of urosepsis in the light of the deceased's medical history. If a CT scan had not shown a stone, a ureteroscopy would have been needed to establish that no stone was present, given that the deceased was continuing to experience symptoms. A reasonable and responsible body of practitioners would have carried out the procedure in all the circumstances. The defenders deny that, but for the alleged negligence, the deceased would not have undergone the ureteroscopy on 23 September 2013.

Objections

[8] The defenders objected to questions directed at discovering what Ms Seaward, Mr Baird and Professor McClinton would have done, or the views they would have taken, if they had been reviewing the X-rays on 5 August as Dr Henderson had been. I allowed the questioning subject to competency and relevancy. There is no case of fault against Dr Henderson. The issue in this case is whether Ms Seaward failed in the duties of care incumbent on her on 23 September 2013. I now sustain the objection on the basis that the view that might have been taken on 5 August is irrelevant to the matters I require to consider. There is no criticism on record of Dr Henderson. Nothing turns on my decision

regarding the objection. There was nothing different involved in the task of assessing the two X-rays on 5 August from that involved in the task of assessing them on 22 or 23 September. There is no real dispute as to what the correct assessment of them was. There is no suggestion that Ms Seaward erred materially in her own assessment of them. What is at issue is what she ought to have done on 23 September in the light of that assessment.

[9] The pursuer objected to evidence volunteered by Professor McClinton in response to an unobjectionable question. One of the points at issue in this case is whether the deceased should have been advised that she was at heightened risk of sepsis given her previous history of postoperative sepsis. The line of evidence concerned the different natures of the procedures undertaken and/or the different circumstances in which they were carried out, respectively in 2011, 2012, and 2013. Professor McClinton proffered those differences as an explanation for his conclusion as to why the episode in 2011 did not indicate increased risk of a similar episode in 2013. There was no record for such differences providing an explanation as to differing levels of risks of sepsis. I sustain the objection, and have disregarded the line of evidence. Again, however, nothing turns on this. One of the points at issue in this case was whether the deceased should have been advised that she was at heightened risk of sepsis given her previous history of postoperative sepsis. For reasons set out elsewhere in this opinion, I am not satisfied that there was any duty to give her advice in those terms. My conclusion on that point is not informed in any way by this passage of Professor McClinton's evidence.

Evidence

[10] The pursuers led evidence from Ms Roberta McNab, Ms Lisette Seaward and Mr Andrew Baird. The defenders led evidence from Professor Samuel McClinton. Professor McClinton was in court during the evidence of Ms Seaward.

[11] The terms "stone" and "calculus" and their respective plural forms were used interchangeably by counsel and witnesses, and I have used the terms employed by the witnesses as they used them in their evidence.

Evidence for pursuers

Ms Roberta McNab

[12] Ms McNab was the sister of the deceased. She gave evidence that she and her siblings formed a close family. She saw the deceased or at least spoke to her every day. She lived near to the deceased. Each regularly visited the home of the other. Before attending hospital for the procedure in 2012 and 2013 the deceased found the prospect terrifying. Because of what had happened in 2011, she was absolutely petrified of hospitals and of having a general anaesthetic. If she could have put off going to hospital she would have done. Ms McNab attended hospital with the deceased on one occasion in 2012, when the deceased had an appointment with a urologist. The doctor asked the deceased how she was feeling, and whether she had any questions. The deceased said she did not, but that she was terrified. He said that she would be fine, that precautions would be in place, and that lightning did not strike twice.

[13] The last time that Ms McNab saw the deceased was on the Sunday preceding her operation. She had been at Ms McNab's house for dinner. At that time she did not look "too well". She was pale and withdrawn and said she had a "niggle" at her kidney.

Ms McNab asked the deceased whether she was sure that she needed the procedure, and whether she was "going to be all right to go in", and she replied that she had no option. Ms McNab understood the deceased to mean that she had ongoing pain. She had had infection after infection and she was wanting to get to the bottom of it. Ms McNab explained further her understanding of the deceased's thinking in the following way. "They" had said that there was "a stone there in the kidney". The deceased was going into hospital to have it removed, although "it didn't turn out that way". The deceased had thought, "If I go in and get this done, that will be it."

[14] The deceased telephoned Ms McNab on the Monday evening following the procedure. She asked her to take pain relief to the hospital because she was in agony. Ms McNab thought the hospital had not had the deceased's usual medication. Ms McNab was not able to drive, as she had had a consultation with a doctor about her eyes that day. She told the deceased to get hold of a nurse and to tell staff how much pain she was in, as they would be able to provide her with something for it.

[15] Ms Doherty suggested to Ms McNab that the deceased had no particular reason to be afraid, given that she had an uneventful procedure in 2012. Ms McNab responded that it was always at the back of the deceased's mind that "the same scenario" (that is complications similar to those she experienced in 2011) "could happen again". Ms McNab did not think that it was something easily forgotten. Although she accepted that the deceased had sought help in summer 2013 and thereafter because she was in pain, she maintained that, knowing her sister as she did, she thought that if the deceased had been made aware of the risks, and those were high risks, she would not have gone ahead with the procedure. She went on to say that it was the "general anaesthetic side of things" that

frightened the deceased. Ms McNab did not know in what terms risk had been explained to the deceased in 2012.

[16] The pursuers submitted that Ms McNab's evidence about the telephone conversation between her and the deceased on 23 September included an account that the deceased said, "You will never believe it, they did not find a stone." The defenders submitted that they had no note or recollection of such a passage of evidence. My own notes do not include that passage. I have checked the audio recording of Ms McNab's evidence. I have not been able to find the passage of evidence referred to by the pursuers. Ms McNab was a softly spoken witness. There may have been a misunderstanding of the passage of evidence to which I refer in paragraph 13. Ms McNab's evidence about the deceased's condition when she last saw her, what the deceased said on that occasion, and what Ms McNab understood her to mean, was given mainly after her account of the telephone conversation of 23 September, which might provide a context for such a misunderstanding.

Ms Lizette Seaward

[17] Ms Seaward is 56 years of age. She qualified as a doctor in 1986, and as a consultant in 1997. She has been working in the United Kingdom as a locum consultant, and then employed consultant, since 2000.

[18] Under reference to the deceased's medical records, Ms Seaward explained that the deceased presented at Glasgow Royal Infirmary on 18 July 2013 and was seen by a locum senior house officer, Dr Anna Crow. The presenting complaint is noted as "? renal colic". The notes record that the deceased had been woken from sleep at 4am with "severe right sided loin -> groin pain". They record also a previous episode of calculi (with the date wrongly noted as 2001 rather than 2011), that the deceased had had a ureteric stent and that

she had subsequently developed sepsis. She had an X-ray of the kidneys, ureters and bladder. Although Dr Crow noted that there were no obvious calculi, a further note, timed at 1315 hours on 18 July 2013 records the presence of a 4mm calculus.

[19] Ms Seaward accepted that X-rays were less effective than CT scans in disclosing the presence of renal calculi. As to the measurement, she explained that the dimension recorded was the longest one that it was possible to measure. That might be quite a subjective judgment, even where a CT scan was used. It might be necessary to have a meeting with the radiologist to come to a view about size. The software used provided a tool for measurement.

[20] An entry at 1325 hours records that the deceased was reviewed by urology, that she was commenced on antibiotics and intravenous fluids, and that urinalysis showed "large blood and protein ++". Ms Seaward confirmed that those findings were often associated with kidney stones.

[21] On 19 July 2013 a note timed at 1540 hours confirmed that the deceased had been seen by Mr Crooks and Dr Henderson, of urology. The note read "Tx as passed renal calculi plan:- stop Abx as no clinical indication for same …" Ms Seaward was not familiar with the abbreviation "Tx". It might mean symptoms or treatment. The note indicated that the deceased had passed kidney stones, as the use of "calculi" denoted the plural, and that antibiotics were to be stopped as there was no clinical indication for them. Warfarin was to be restarted. From the point of view of her urological condition, the deceased could have been discharged at that stage, but was kept in hospital because of problems relating to blood clotting.

[22] A letter from Dr Henderson to the deceased's general practitioner following the appointment on 5 August 2013 recorded a diagnosis of a 6mm VUJ (vesico-ureteric junction)

calculus, and that the deceased had been placed on the waiting list for a right rigid ureteroscopy. She was to remain on Tamulosin in the meantime. Ms Seaward explained that this medication was intended to dilate the urine tube for easier passage of the calculus. There was controversy over its use. Half of the literature on the subject said that it was of no use whatsoever, and half said that its use was indicated for calculi measuring between 5.5mm and 1cm. The letter concluded:

> "She is having ongoing niggles in her right iliac fossa and her stone persists on KUB. I have asked her to continue on her alpha blocker and think it is likely she will require to have a right rigid ureteroscopy as a day case to get rid of her stones."

[23] Ms Seaward's own view of the X-ray taken on 5 August was that on first sight there was no obvious calcification visible in the area where the earlier X-ray disclosed a stone. After a very careful viewing on a larger screen Dr Henderson might have thought that a stone was present but not of the same density. When Ms Seaward had reviewed the X-ray "it was dubious" if there was the calcification clearly indicated by Dr Henderson. Asked about why the deceased was being reviewed after discharge, given the record that she had passed a stone or stones the day after she was admitted in July, Ms Seaward said that the deceased's general practitioner had been in touch regarding review.

[24] Dr Henderson had explained to Ms Seaward, after the procedure, what it was that she had thought was a stone. The quality of the image was better on the screen they had used than that available in court. She had been able to see what Dr Henderson was referring to. There would have been no reason to give Tamulosin if the stone had passed. If a stone had been passed in hospital, it would have been sent for analysis. There was no indication that had happened.

[25] Ms Seaward was asked whether there would be any reason for a stone present on 5 August to be less clearly visible on the X-ray than that on the earlier X-ray. She said that there could be a wide variation in the intensity of different X-ray machines. That would not, however, explain the difference between the two X-ray images.

[26] Ms Seaward first saw the X-ray of 5 August in the late afternoon on the day before the procedure. She also had the 18 July X-ray available. She discussed the matter with colleagues. Her impression was that the calculus shown on the 18 July X-ray was not visible on the 5 August X-ray. She told the deceased that she could not confidently identify the calculus on the X-ray. She told her that it would be in her best interests to have a CT scan performed rather than going ahead with the planned procedure. If she had been in Dr Henderson's place on 5 August, her interpretation would have been that she could not see the stone clearly on the X-ray. Her recommendation would have been a KUB CT scan.

[27] Ms Seaward had provided written answers to questions in relation to the present litigation. In doing so she had quoted directly from a letter that she had composed responding to a complaint against her regarding her treatment of the deceased. She said she had composed it within 9 weeks of 23 October 2013. The letter itself was dated 25 November 2013. It included the following:

> "[The deceased] had ongoing R loin pain and was seen by Dr Nicola Henderson at GRI and was listed for a right ureteroscopy and laser stone fragmentation. She had a review KUB on 5/08/2013 which did not show an obvious calcification and on the morning of her admission I did discuss the KUB findings with Mrs McNab. I thought she had passed her calculus. She was distressed and complaining of sever [sic] R loin to groin pain and back pain, She was severely distressed when I wanted to cancel the planned procedure. According to her she had the same ongoing sever [sic] R loin pain and had to take pain medication all the time.
>
> Eventually I did perform her consent and explained the right rigid ureteroscopy, right retrograde pyelogram and possible insertion of a right J-

> stent. I did consent her with regards to the potential risk of the procedure including urosepsis as she had a history of previous urosepsis."

[28] In her oral evidence Ms Seaward confirmed that her opinion had been that the most likely explanation for the appearance of the 5 August X-ray was that the calculus had been passed. Mr Clarke suggested that if that were the case, the procedure could have provided no benefit to the deceased. Ms Seaward responded that the deceased was complaining of ongoing pain. A calculus was not the only possible reason for the pain. The deceased had had previous procedures and had had a stent fitted. Asked to recall as best she could what she said to the deceased, Ms Seaward said that she based her evidence on what she had recorded in the letter dated 25 November 2013. She had discussed her findings with the deceased. The deceased had been complaining of pain. Ms Seaward gave her the options of having a scan, or proceeding to look in her urine tube. The size of a stone was not always relevant. Clinicians could assume that a stone was completely gone but on imaging weeks later there could be a small part of the stone remaining.

[29] She explained to the deceased that there were risks associated with the planned procedure. To do so was part of her normal practice. The deceased was known to have had sepsis on an earlier occasion. She assumed the deceased would therefore understand what sepsis was, perhaps better than other patients. She counselled her as to the risks of infection, urosepsis, injury and a planned second procedure. She explained to the deceased that the deceased had been led to believe she had a stone, but that she, Ms Seaward, did not believe that there was a stone. She explained that it would be in her best interests to have a CT scan, but the deceased was in pain and distressed, and wanted the procedure. Ms Seaward explained to the deceased that in the event that she chose to have the procedure, it might be possible to determine whether there was other pathology. She could not remember

specifically if she had told the deceased that the procedure might have no benefit. She told the deceased that she could not see any obvious calculus and there was a high index of suspicion that she had passed it.

[30] The deceased was weeping. She said she was in acute pain and needed to take pain killers all the time. When Ms Seaward suggested cancelling the procedure, she became more distressed. Asked whether she was satisfied that the deceased had understood her advice, she said the following. She had explained the procedure, her findings, and the potential risks, and the deceased had signed the consent form. She and her colleagues often operated on people who were experiencing severe anxiety and distress. The deceased was complaining of severe pain which she said was the same as that which she had had previously from renal stones. She distinguished it from other pain which she had from fibromyalgia. Ms Seaward had told the deceased about the risks before the deceased signed the consent form.

[31] The consent form the patient signed did not record the discussion that Ms Seaward described in evidence. She said that it was her practice at the time to record the detail in the final discharge letter. She had dictated a letter in theatre on the day of the procedure, reporting that no calculus had been found, but not recording the discussion leading to consent. She explained that that was not the final discharge letter, it merely recorded what had been done in theatre on the day in question. She had not discussed matters with the junior doctor, Dr Alistair McKay, who had been in theatre with her that day. The letter dictated in theatre records:

> "While on the table right retrograde pyelogram did not reveal any further calcifications within the right renal tract. Rigid ureteroscopy done from the right UO to the right PUJ and no further calculi seen."

[32] In cross examination Ms Seaward explained that a ureteroscopy involved the patient being fully anaesthetised. The ureteroscope was introduced into the bladder and ureter. If the ureter was flexible, the ureteroscope was used also to visualise the kidney. Renal stones were amongst the most common complaints for which she required to treat patients on an emergency basis in her practice prior to 2006, with one or two presenting each week. She had continued to treat stones throughout her career, and in 2010-11 she had become one of two "stone surgeons" employed by the defenders. She performed between six and ten procedures each week. Those included ureteroscopy, diagnostic work, and treating blood in the urine, and tumours of the kidney.

[33] Ms Seaward said that she remembered the deceased's case very well.

[34] Ms Doherty asked Ms Seaward about entries in the medical records relating to the deceased's earlier admissions. A note dated 3 October 2011 recorded that a CT scan had disclosed an 11mm calculus – a renal calculus sitting between the kidney and the urine tube. The operation note dated 4 October 2011 disclosed that the operation on that occasion had been the insertion of a right J stent. There was nothing to indicate the stone had been removed, or that any attempt had been made to remove it. The notes also recorded that the deceased had been admitted to the intensive care unit for management of respiratory failure following urgent ureteric stenting, and that she had completed a course of intravenous antibiotics after growing EBL in her urine. She had been discharged on 17 October 2011 with a diagnosis of heart failure. The discharge letter, from a cardiologist, narrated that the cause of the deceased's deterioration was heart failure due to severe left ventricular systolic dysfunction, and that she had responded well to treatment.

[35] The admission in April 2012 had been for urolithiasis (a right renal pelvic stone said to measure 1cm). The procedure was recorded as "right flexible ureteroscopy, laser, change of stent". The follow-up was to be the removal of the stent after one to two weeks.

[36] The records produced as 7/3 of process included a handwritten annotation at page 3, with the date "5/8/13" handwritten beside the printed words "Follow up arranged: Urology 2/52". In relation to the admission in July 2013, a note timed at 0930 hours on 20 July recorded that the deceased's pain had resolved, but she would need to remain as an inpatient because of her INR (a measure of blood clotting).

[37] In relation to each of the earlier procedures the same type of consent form had been used as in September 2013.

[38] Asked about the record of the preoperative assessment dated 4 September 2013, she said that its purpose was to capture all the relevant information with regard to the prior and current history of the patient, and the medication the patient was taking. It set out what investigations were required before the operation, which included a full blood count, echocardiogram, urea and electrolytes (for kidney function) and thyroid function tests. It was not routine practice in 2013 to take preoperative urine cultures. Ms Doherty asked Ms Seaward about *Guidelines on Urolithiasis* published by the European Association of Urology in 2013, which stated that a urine culture or microscopy was mandatory before any treatment for stone removal was planned. She said that a dipstick test was the equivalent of microscopy, and that that was routine prior to the procedure.

[39] The preoperative assessment included a good deal of information about the deceased's cardiac history. No further imaging, either X-ray or CT, was undertaken or ordered at the time of the preoperative assessment. In Ms Seaward's view that was because the July X-ray had shown a stone. The deceased had then attended on 5 August and been

told that the stone persisted, and on the day of the procedure she had ongoing significant right loin pain. The nurse who carried out the assessment would not in any event have had authority to order imaging. The anaesthetic record for the procedure recorded the results of the investigations ordered at the preoperative assessment. These were normal. The deceased's anaesthetic risk score ("ASA") was recorded as "3". A figure of "1" denoted normal, and one of "3" denoted a patient with more than one comorbidity or significant comorbidity. The admission observations and preoperative instructions form recorded that the dipstick test had indicated a trace of protein in the deceased's urine. That had not been of concern. It did not indicate infection, and did not indicate that a culture was required. It was standard practice to do a dipstick test on the morning of the procedure, and usual practice to proceed with the operation in the light of the result.

[40] Ms Seaward gave further evidence regarding urine cultures. They were not routinely taken. If urine cultures were needed before an elective operation, patients were normally (since about 2015) requested to hand them in 10 days before a procedure, to allow for the results, and for treatment and a further sample if needed. The defenders' microbiology service took about 48 hours to provide the results from urine cultures both as at the date of proof and in 2013. The deceased had had a urine culture taken during the July 2013 admission. It showed no significant growth.

[41] Ms Seaward had not met the deceased before the morning of the procedure. She had suggested postponing the operation because CT imaging could provide 94% sensitivity as to the presence of a small stone. That would have caused a delay. At the relevant time it would have taken about three to four weeks to arrange the scan. It would be reported about two to three weeks after it had been taken. If there was still a stone present at that time, the patient would be relisted for her planned procedure. That would involve a further wait of

two to three weeks. It was fairly frequent for patients to complain of pain but for there not to be a stone clearly visible on imaging. Sometimes a patient would have a CT scan, or scans separated by some weeks, disclosing a small stone. They would still have pain, have a ureteroscopy, but no stone would be found during the procedure. A situation where a patient had pain, but no clear image of a stone on X-ray would occur around once every four months. In situations of this sort, Ms Seaward's practice was to discuss the imaging, and ureteroscopy to see whether there was any alternative pathology contributing to the pain. That would be the practice of her colleague Mr Jones, with whom she had a close working relationship.

[42] Even CT scanning was not one hundred percent accurate. It did not always reveal a stone when a stone was present. If there was a CT scan where no stone was demonstrated and the patient had pain, again, Ms Seaward would discuss the results of the imaging, and, depending on the patient's symptoms, and in particular the pain score, would advise as to the availability of ureteroscopy.

[43] Ms Seaward's evidence was that she did not recall each word of her discussion with the deceased, but that she did recall the discussion about the risks and benefits of proceeding as against deferring the procedure. Ureteroscopy had the possible diagnostic benefit of determining the presence of pathologies other than stones. If there was an alternative pathology, in the majority of cases, that could be dealt with during the procedure. Asked specifically what she had said to the deceased about the risk of sepsis, she said that she had advised that any patient who had any urinary tract infection before, and a patient with any complicated stone procedure with any infection or sepsis would be at high risk for sepsis on a second planned procedure. Ms Seaward could remember no situation in which she had not explained the risks and benefits of a procedure to a patient.

[44] Asked about the letter dated 25 November 2013, she said that her recollection at the time she wrote it had been good. She had been very distressed about the matter. She had, however, told the deceased about risks that were not specifically mentioned in the letter, namely the increased risk of urosepsis. She had also told her about the risk of bleeding, of uretheric injury, of a second planned procedure, and of irritation or pain if a stent were required. She had provided more detail in her "response letter", which related to the present claim, and which she had written in 2016, in the following terms:

> "I did consent her with regards to the potential risk of the procedure including urosepsis. It is my normal practice to consent all patients for any ureteroscopy or retrograde pyelogram with regards to the risk of infection, sepsis, bleeding or unable to gain access to ureter or stone, utereric perforation and stent irritation. Although not documented in the case notes all these risks were explained prior to obtaining consent."

[45] Ms Doherty pointed out that the preceding passage did not mention advice about an increased risk of urosepsis. Ms Seaward responded, "I think at the time it was just such a lot of documentation". Asked about the consent form, Ms Seaward said that, at the time, consent forms did not have a specific heading inviting recording of the risks discussed. The forms had since changed. The deceased had died before Ms Seaward had prepared a detailed discharge letter detailing the discussion. She was one hundred percent confident that she had explained the risks and benefits of, and alternatives to, the procedure. The deceased had had severe right loin pain. If she had not been complaining of pain, Ms Seaward would have cancelled the procedure. She had been satisfied that the deceased understood what she was telling her. At the end of the discussion, before a patient signed, it was her habit to run through everything again. She would keep the form in front of the patient, and ask them to explain to her what they were going to "have done".

[46] It was put to her that there might in fact be no increased risk of sepsis because of the event in 2011. She said that if a patient had had any episode of urinary tract infection, if they were diabetic, or if they had previously had a stone with associated infection or sepsis, she would always advise that they did have an increased risk of infection. She accepted that there might not in fact be such an increased risk. In ureteroscopy generally the risk of sepsis was about 0.3%. She did not accept that she should have refused to carry out the surgery without a CT scan. She maintained that since 2010 it had been her understanding that she needed to explain all the potential management plans that she could offer. In this case those had been either a CT scan or ureteroscopy.

Mr Andrew Baird

[47] Mr Baird is a consultant urological surgeon in the department of urology at University Hospital Aintree, Liverpool. He currently works there, at Alder Hey Children's Hospital and at Sefton Hospital, a private hospital in Liverpool. His particular speciality is in functional and reconstructive surgery, particularly adolescent urology and the functional outcome of reconstructive surgery in childhood. He qualified as a doctor in 1995 and gained the qualification of FRCSUrol from the Royal College of Surgeons in Edinburgh in 2006. He adopted his report, number 6/14 of process, as his evidence.

[48] Mr Baird had viewed the July and August X-rays. The July X-ray showed a stone in the line of the ureter, measuring 6mm by 2 or 3mm. The August X-ray, when compared with the July X-ray showed that the stone had passed. It was no longer visible on the X-ray. The image on the July X-ray had been very clear, and there was no doubt the stone had been present. Given the clarity and quality of both X-rays, the stone, had it been present, would have been visible in the same position or lower down, which it was not, on the August

X-ray. It was only possible to take two-dimensional measurements of a stone. The third dimension was extrapolated from those measurements, and would have been about 2mm. It was not likely that the stone would turn around. It would remain in the same dimension within the ureter. The X-ray of 5 August was completely normal and there was no stone in the line of the urinary tract to left or right. It was likely that the stone had completely passed. At a later stage in his evidence he said that, looking at the two X-rays, he would be 95% certain that the stone had cleared.

[49] Mr Clarke asked whether the fact that the deceased had had a serious complication in 2011 after "this procedure" gave rise to an increased risk of complication. Mr Baird stated that it was his opinion that it did. He did not accept that the risk of complication was diminished by the circumstance that the deceased had had an uneventful procedure in 2012. The second procedure might not have been carried out under general anaesthetic, but that would not alter the risk from the procedure itself, although it would reduce the risk of cardiac and respiratory complications. In cross examination he accepted that the records showed that the 2012 procedure was, in fact, carried out under general anaesthetic.

[50] The documented risk of sepsis in relation to the procedure was said, in patient information prepared by the British Association of Urological Surgeons, to be 1-2%. The risk of catastrophic sepsis was lower than that. It was difficult to provide a percentage risk figure for a patient who had already suffered an episode of sepsis, but in general it would be necessary to multiply the figures already given "several times".

[51] In his opinion, it was not sufficient to take a dipstick urine test on the day of the procedure. It did not replace the detail that would be provided in a culture report relating to a urine sample. A dipstick used chemical reagent to detect white blood cells, protein and nitrites, and was a screening test. It was not a laboratory based test and would not detect

low levels of bacteria. It had reasonable sensitivity but was not infallible. If a urine sample had been taken at the preoperative assessment it would have provided an opportunity to treat any infection, and for a reasoned choice as to the antibiotic used.

[52] His reading of the case was that Ms Seaward was in doubt as to whether the stone was present or absent on the day of the procedure. At that point it became imperative that she obtain a CT scan, given the history from 2011. Comparing the two X-rays clearly demonstrated that the stone had passed, and he would have recommended a CT scan. The deceased had a history of stones, she had convincing symptoms, and a stone had previously been shown. In the light of the August X-ray, the correct course of action would be to perform a CT scan to confirm the absence of any other stone material. That would have been what he would have recommended on 5 August. Had he encountered the deceased immediately before the elective operation, with the July X-ray showing a stone, and the August X-ray showing it had passed, he would have recommended postponing until a CT scan had been obtained, rather than putting her at risk of complications from the procedure.

[53] Consent was a process, rather than a single moment in time at which a patient gave permission. Good practice involved the discussion of risks in procedure, alternative methods of treatment and often the use of written material provided so that the patient could absorb the contents and ask questions about it. It ended with the signing of a consent form. The only evidence of the consent process in the notes was the signed consent form. There was no written record of the discussion of the alternatives or the risks in this case.

[54] In his opinion, bearing in mind the deceased's history of having "unwanted effects" from a procedure, and his belief that the stone had passed, subjecting the deceased to a ureteroscopy "just to see" was the incorrect course. If a CT scan had suggested there was an

abnormality then, following discussion of the risks involved, it would be appropriate to go ahead with a ureteroscopy. A CT scan would have picked up small fragments, and would have been the appropriate course if there were a suspicion that fragments remained. There could have been no suspicion that a stent was causing irritation, as the patient did not have one in place at the time.

[55] Mr Baird was of the view that Ms Seaward failed in her duty of care to the deceased in being persuaded to proceed with the procedure. The correct clinical decision would have been to refuse to do so, and to reschedule following a confirmatory CT scan. Had that happened, the CT scan would, on the balance of probabilities, have confirmed the absence of a stone, and the procedure would not have been carried out.

[56] There did not need to be any symptomatic infection for sepsis to occur following surgery. The instrument had to pass through from the outside and into the ureter, and there was ample opportunity for bacteria to enter the bloodstream from urine. Stone fragments contained millions of bacteria. The use of gentamicin as a prophylactic antibiotic had been appropriate.

[57] In Mr Baird's opinion an ordinarily competent urological surgeon would have taken into account the previous serious complications in 2011 when deciding on treatment in 2013. Such a clinician would have considered a CT scan to confirm the continued presence of the stone before submitting the deceased to a ureteroscopic procedure carrying "considerable risk". There was no documentation of any discussion regarding risk. That practice had been departed from in that Ms Seaward had failed to establish beyond doubt the presence of a stone and in that she had failed to carry out a "robust consent process".

[58] In many ways it was a difficult decision to cancel a planned procedure on the day. Patients would have built themselves up, and arrived in a heightened state of anxiety. A

theatre team would be in place, and it would be difficult to "go back", but the clinician's professional responsibility was to safeguard the patient, and if the correct course was to cancel or postpone, that should be done.

[59] He accepted that there would be clinicians who would still proceed, albeit that he thought that was the wrong approach in the case of a patient at "high risk of complications" and whose overall health was not optimal. He said that the important factor was that a decision to proceed must be based on a full and frank discussion covering risk and benefit, and that that did not appear to have occurred in the present case. If he were asked what a reasonable body of practitioners would do in "this conundrum" it would be to have the discussion with the patient and document it. The benefit of the procedure, if there were a stone present, would be to clear the stone. If there were no stone, there would be no benefit.

[60] In cross examination Mr Baird said that he had performed about twenty ureteroscopies in the last five years, predominantly to deal with stones. His colleagues who were subspecialists dealt with the vast majority of stones in his department. None of the published papers in his CV related specifically to endourology. He did not, however, agree that a consultant urological surgeon who specialised in endourology was better placed than he was to advise as to normal practice in the clinical decision making as to whether or not to perform a procedure. He said that decision making was within the remit of any urological surgeon.

[61] In his report he narrated that the procedure in 2011 had been to fragment a stone, but he accepted that it had been to insert a stent, although he said that the stent had been inserted to deal with a stone. He had not mentioned in his report the uneventful procedure from 2012. He regarded it as irrelevant to risk, and had been focusing on the questions he had been asked to address in his report. He thought he had included in his report a

reference to the circumstance that the deceased was continuing to complain of pain on 23 September 2013, but was unable to identify any passage where he had included that information. He accepted that it was an important matter in the context of having a discussion with the patient about the risks and benefits of the procedure.

[62] The European Association of Urology guidelines on urolithiasis include a recommendation in the following terms:

> "Urine culture or urinary microscopy is mandatory before any treatment is planned."

He did not accept that a dipstick test could be equated with microscopy. While it might have been normal practice in the defenders' hospital to do a dipstick test it was not his normal practice nor that of his hospital. In his hospital it was normal practice to insist on microscopy for every patient undergoing ureteroscopy, and had been since 2007. He thought that most consultant urologists who were endourologists would have insisted on microscopy in 2013. He accepted, however, that as a matter of generality they would possibly have proceeded on the basis of a clear urine dipstick, in the absence of microscopy. In a patient such as the deceased who had had a prior catastrophic episode, they would not rely on a general screening test such as a urine dipstick.

[63] Mr Baird accepted that CT scans were not one hundred percent accurate, and that in some cases they would not detect the presence of a stone. He said that they would do so in the vast majority of cases. The stone in this case had been easily seen on a plain X-ray, and would have been guaranteed to show on a CT scan. It was in principle possible for a stone to move so as to be less visible on imaging, but he did not accept that that would have happened in this case. He accepted that it would be relevant that the deceased was

distressed by severe pain in the area where it had been at the time of the July X-ray, and that the pain related to the stone so far as the patient was concerned.

[64] He did not accept that where there were continuing symptoms, even where it was thought that the stone had passed, ureteroscopy would be the only way to establish the patient was in fact stone free, because he was of the view that the stone, if present, would have shown on a CT scan.

[65] He accepted that the risk he had mentioned, of 1-2%, was the risk of symptomatic urinary infection, rather than sepsis, and that was what he meant to convey. Sepsis occurred in 0.3-0.5% of cases. He agreed with Professor McClinton's assessment that the deceased was at high risk because of her age, because she was female, and because she was assessed as an anaesthetic risk at level 3.

[66] Ms Doherty asked whether it would be sufficient simply to give someone in the deceased's position advice that there was a small risk of sepsis associated with the procedure. Mr Baird's opinion was that to offer standard advice on the risk of infection and sepsis would be to offer an unrealistic view of risk in her particular case. Although she had an uneventful procedure in 2012, she had had a very eventful procedure in 2011, and that had demonstrated a higher than average risk. That was a real and material risk that was not discussed with her in 2013.

[67] He did not think there was literature to support the proposition that the risk that applied generally required to be multiplied several times. It was his opinion, and there was no evidence in the published literature to support it. There was no evidence in the published literature one way or the other as to whether there was an increased risk of sepsis.

[68] Mr Baird maintained that he would have refused to carry out the procedure. He summarised his position by saying that there were two options. One was safe, and the other

was "highly risky". The latter was taken, and the patient died. Obtaining a CT scan and cancelling the procedure was the only reasonable treatment option for a patient with the deceased's medical history. It was his responsibility as a clinician to make the decision in the interests of the patient. He accepted that ureteroscopy might have a benefit in establishing the absence of a stone, but would have no clinical benefit. He thought it unlikely that it would disclose some other pathology that would explain the pain.

Professor Samuel McClinton

[69] Professor McClinton is a consultant urological surgeon who formerly carried out clinical work at Aberdeen Royal Infirmary. He was appointed to that role in 1993. He retired from NHS clinical work in 2016, and from all clinical work at the end of 2017. He provided a subspecialist service in laparoscopy and stone surgery. He normally had three lists a week which would be purely stones, whether kidney stones or stones in the ureter. He would deal with about two hundred cases of stones in the course of a year. He was elected president of the Scottish Urological Society in between 2006 and 2008 and was chair of the endourology section of the British Association of Urological Surgeons between 2007 and 2009. Almost all of the publications listed in his CV related to the management of stones, particularly those published in the last five years. He continues to work part-time in research.

[70] Like Ms Seaward and Mr Baird, Professor McClinton was able to see a stone with a dimension of about 6mm on the July X-ray. In his view there was no clear evidence of a stone on the August X-ray. That would be explained by the patient's having passed the stone, or the stone's having moved so that it was more difficult to see. Stones were not

round, and might be faceted. They might be thin and look more obvious on one plane than another. On most occasions one would use a CT scan because it had a higher sensitivity.

[71] Professor McClinton explained that the ASA score was an assessment of general fitness. The higher the score, the more at risk the patient from an anaesthetic perspective. A person with a score of four would not be a day case. It was not normal practice to order urine cultures. If the deceased had had an infection in July, that would have been an indication for a urine culture, but it was not something done as a matter of routine. The dipstick test on the day of the procedure was an indication that there was no ongoing infection. His evidence was that all units would do a dipstick test on the morning of the procedure in 2013, and that that remained the position. Referred to the guidance he said that a dipstick test was a rapid way of "doing the same thing as" microscopy. He said that it had been shown to be equivalent in terms of picking up infection. Most consultants would consider it safe to proceed with a negative dipstick test.

[72] The only imaging that might have assisted in the present case would have been a CT scan. In most units it was not feasible to do that on the day of the planned procedure. CT scans would disclose a stone in about 95% of cases. He referred to a paper, *Systematic review and meta-analysis of the diagnostic accuracy of low-dose computed tomography of the kidneys, ureters and bladder for urolithiasis*, Hao Xiang and others, Journal of Medical Imaging and Radiation Oncology 61 (2017) 582-590, which provided a figure of 93.1%. Stones in the pelvis could be more difficult to image. The "pooled" figure for sensitivity related to all stones, but the figure for stones in the lower third of the ureter dropped to 90%. The stone in the present case, when seen on X-ray, had been in the lower third of the ureter. There was no guarantee that a stone would be disclosed on a CT scan. CT scans were not in that

respect infallible, although they provided the best imaging available. They involved an exposure to radiation which ought not to be undertaken unless necessary.

[73] The options for Ms Seaward on 23 September, given that the deceased was complaining of symptoms of pain, and had had a stone that was visible on X-ray in 2013 were these. She could have sent the deceased for further imaging, in the hope that that would provide further information. Alternatively, she could proceed with the planned procedure and directly visualise whether or not the stone was present. As the patient had symptoms, she could not exclude the possibility that either the same stone, or part of it, was still present. He had one case about every six weeks in which there was some dubiety about whether or not a stone was still present.

[74] If a CT scan had been obtained, it would have shown no stone, if one accepted that the ureteroscopy had shown no stone. If the CT scan had not disclosed a stone, but the patient continued to complain of pain, then a ureteroscopy would be suggested, in order to see whether the stone was still there. If a patient had symptoms which were in keeping with a stone, and if the patient had had a stone before, they would usually be good at knowing whether they had another stone. A discussion would take place, and the clinician would offer the options of waiting for a couple of months or proceeding to "have a look". There was no published guidance as to what to do when a stone was no longer clearly shown but the patient still had symptoms.

[75] An explanation to the patient as to the risks of bleeding, infection, stent irritation, a planned second procedure and an increased risk because of her medical history would be a "standard approach", except that Professor McClinton would not have said that there was an increased risk of sepsis. The benefits of the procedure would be that it would disclose whether or not there was still a stone, or part of the stone, in place, or whether there must be

other causes for the pain. Someone with previous stents and stones could develop narrowing and scarring of the ureter from the passage of stones and instruments. The exclusion of a stone as the cause of pain would be of benefit insofar as it clarified the position for the patient and the clinician. A negative result was not of no benefit to the patient. If Ms Seaward had told the deceased that she could not confidently see a stone, and that having a ureteroscopy might determine whether there was other pathology, he would regard that as a reasonable explanation as to the potential benefit of the procedure.

[76] Professor McClinton read out and adopted the first paragraph of the conclusions section of his report, which is in the following terms:

> "With regard to consent in this case the patient should have been warned about the normal risks of a ureteroscopy and Ms Seaward avers this was her normal practice. There is no heightened risk of sepsis in this case because she had a previous episode of sepsis following intervention for a stone as proven by the fact that she had subsequently had a further intervention with no problems at all. Her urine dipstix prior to surgery did not show any evidence of infection. She was at higher risk of sepsis because of her age, the fact she was ASA 3 and had a history of urinary infection in the past. Normal practice would be to give antibiotic prophylaxis to reduce the risk of infection and sepsis and this was given appropriately in this case."

[77] As to the risk of infection and sepsis generally, he referred to an article, *Complications associated with ureterorenoscopy (URS) related to treatment of urolithiasis: the Clinical Research Office of Endourological Society URS Global Study*, B K Somani and others, World J Urol (2017) 35:675-681. That contained a table listing post-operative complications. It provided a percentage figure of 0.95 for urinary tract infection and one of 0.3 for sepsis. Infection was a more common occurrence than sepsis. Sepsis was an abnormal reaction to infection, and was much rarer than infection itself. He would normally quote an infection rate of between one in fifty and one in a hundred. He thought that the figure of 0.3 was probably high. The study to which the article related was a worldwide study, and some countries had lower

standards of hygiene and healthcare than those in the United Kingdom. He had just completed a study of three hundred cases in which there had been no episodes of sepsis.

[78] The deceased's episode of sepsis in 2011 was related to an obstructed and infected system for which she had an urgent stent. In that setting the risk of sepsis was much higher. That did not mean that she was likely to have the same reaction in the context of a planned procedure, and to which I have already referred. The foregoing was the passage of evidence to which objection was taken. There was no evidence to support the proposition that she was more at risk of sepsis because of the incident in 2011. He disagreed with Mr Baird's proposition that the risk should be multiplied several times. The risk of infection from ureteroscopy arose from the possibility that by putting an instrument into the system, bacteria could be pushed into the blood stream. That was why prophylactic antibiotics were used.

[79] In relation to his opinion that the deceased was at higher risk of sepsis because of her age, ASA score and history of urinary infection, he referred to a further article, *Postoperative Infection Rates in Patients with a Negative Baseline Urine Culture Undergoing Ureteroscopic Stone Removal: A Matched Case-Control Analysis on Antibiotic Prophylaxis from the CROES URS Global Study*, Alexey Martov and others, Journal of Endourology Vol 29, Number 2, February 2015: 171-180. The purpose of the study had been to discover whether the use of antibiotics made a difference to outcomes. It provided figures for the prevalence of certain outcomes in both control groups, and information as to factors that appeared to influence the outcomes. The abstract contained the following:

> "The prevalence of fever and UTI was low (≤ 2.2%) and similar in both groups. Factors predictive of postoperative UTI or fever were female gender, Crohn's and cardiovascular disease, a high stone burden and an ASA score of II or higher."

[80] The deceased would have had the same risk factors for infection in 2012 as she did in 2013. The risk of sepsis might be in the region of 0.6 or 0.7%. It was higher than the risk applicable generally, but still a low risk. He would simply have given the deceased standard advice, because the increase in risk was small. He would say there was a risk of infection and sepsis, but not go into any greater detail than that.

[81] The deceased should have been advised of the alternative to proceeding, namely postponing to obtain a CT scan. A reasonable and responsible body of practitioners would have proceeded if the patient had wished that to happen, and a management plan would in those circumstances be agreed with the patient. Professor McClinton said that he had knowledge of what was normal practice in the urology department of Aberdeen Royal Infirmary. He was in contact with between twenty five and fifty other centres in relation to the studies he worked on. Complications had to be reported back. He often got phone calls about patients in scenarios similar to that involving the deceased on 23 September 2013. A colleague would be asking whether to include such a patient in the study. It was not common, but neither was it unusual for him to have discussions about such situations.

[82] Professor McClinton's view was that the consent procedure was not well-documented. If Ms Seaward had advised the patient in the terms that she said in her oral evidence that she had, that would have been sufficient and in accordance with normal practice. He would not have followed a practice of documenting the consent process in a discharge letter, but would have included something in the notes, given that it was a complex situation. The process of documenting consent had changed considerably since 2013.

[83] He did not consider that there was any duty to postpone the procedure to obtain a CT scan. Both postponing and proceeding were reasonable options. He did not think, as

Mr Baird did, that there was "a correct" clinical decision. His evidence was that patients could get pain after a stone had passed, pain might stop after a stone had passed, and pain could also stop with a stone still in place. When a patient was still complaining of pain, it was reasonable to offer ureteroscopy. The view that it should not have been an option where the stone was no longer visible on X-ray was quite an extreme view.

[84] In cross examination Professor McClinton said that he found it difficult to interpret the entry in the notes on 19 July referring to calculi having been passed. If the clinician thought a stone had been passed, he or she would have arranged an X-ray at the time to confirm. The deceased had been sent home with Tamsolusin, which would have been a waste of time if she had passed the stone. It would not have been prescribed simply to deal with the possibility that some fragments were left. The deceased was to be seen again, and he thought that the assumption was that the stone was seen in place, and would be reviewed to see whether the stone had passed.

[85] Asked whether a niggle in the right iliac fossa would be typical of pain from a stone, he said that pain gravitates from the loin on the back, comes round and travels downwards. Viewing the August X-ray in August 2013, he would have assumed that the stone had passed. He might have ordered a CT scan to clarify matters. The description of niggles did not sound like colicky pain. The level of pain would vary depending on whether or not the stone was moving. One could not infer the depth of a stone from the two dimensional image on an X-ray. The opacity of a stone was to do with its crystalline content, not its size. Professor McClinton disagreed with Mr Baird's view that a stone would be unlikely to change plane in its transit. On the contrary, it would move to where it became caught, and might move and change position.

[86] Regardless of the deceased's condition of fibromyalgia, he would have accepted from her an account that she had pain similar to the pain of renal colic she had experienced before. A feature of colic was that it could be intermittent.

[87] Asked about the statement in his report that the 2012 intervention "proved" that there was no heightened risk of sepsis in the light of the 2011 incident, he said that he had been trying to make clear that the circumstances were different in 2011, 2012 and 2013. The risk on each occasion was different.

[88] In re-examination, he said that he would have hoped that the stone shown in the July X-ray would have been shown in the August X-ray. The stone was big, and quite dense, and he would have expected to be able to see it.

Summary of submissions

Pursuers

[89] Counsel submitted that I should conclude that it was unlikely that the deceased would have refused to follow Ms Seawards advice, given that she was, on Ms McNab's account, reluctant even to ask nurses for painkillers. I should infer that Ms Seaward had not given the advice that she claimed to have given. I should accept that had that advice been given, the deceased would have chosen to have a CT scan and postpone the procedure. Even if advice had been given, I should not be satisfied that Ms Seaward had obtained the informed consent of the deceased. It was unclear exactly what she had said, and I should take into account also that Ms Seaward had a strong South African accent, and the distressed state of the deceased at the time.

[90] The absence of contemporary records told against the credibility and reliability of Ms Seaward. Further, this was a situation in which the defenders had, by reason of the lack

of contemporaneous record regarding consent, made it difficult or impossible for the pursuers to adduce relevant evidence. The defenders therefore ran the risk of adverse findings: *Keefe* v *Isle of Man Steam Packet Co Ltd* [2010] EWCA Civ 683, paragraphs 19-20; *Raggett* v *Kings College NHS Trust* 2016 EWHC 1604 (QB), paragraph 131. No oral evidence had been adduced from Dr McKay, the junior doctor in theatre, who would have heard the deceased being consented. I should draw inferences adverse to the defenders from this absence of evidence: *Gateway Assets* v *CV Panels* 2018 SCLR 736, paragraph 59.

[91] As to informed consent, I required to apply the approach set out in *Montgomery* v *Lanarkshire Health Board* 2015 SC(UKSC) 63, paragraphs 81-90; *Webster* v *Burton Hospitals NHS Foundation Trust* [2017] Med LR 113, paragraphs 26-31; and *KR* v *Lanarkshire Health Board* [2016] CSOH 133, at paragraph 133. On the basis of Ms McNab's evidence, I should find that the deceased would have attached significance to an increased risk of sepsis.

[92] Counsel also submitted, however, that as the case had developed, the explanation of risk to the deceased had become less important. There was no dispute that there was a risk of sepsis which was relatively small in percentage terms. The question I ought to address was what the deceased would have done if she had been advised, in her best interests, not to have the procedure, but to have a CT scan, because Ms Seaward suspected that the stone had passed.

[93] The decision to proceed could not be rationally justified, given that Ms Seaward did not think it in the deceased's best interests: *Bolitho* v *City and Hackney Health Authority* [1998] AC 232, at 241; *Montgomery*, paragraph 61. The present case was more about diagnosis and treatment and the advice given to the patient than about disclosure of risk, and therefore fell into the category of cases identified by Lord Browne-Wilkinson in *Bolitho* in which it would be open to the court to reject the opinions of medical experts on the basis that the

professional practice of which they spoke was incapable of withstanding logical analysis. Mr Clarke suggested that I should regard Professor McClinton as having strayed into advocacy, because he had volunteered information about different risks arising from different procedures, and had continued to volunteer that information in cross-examination notwithstanding an objection from senior counsel taken during evidence in chief.

[94] The defenders asked me to accept Ms Seaward's evidence that she had properly discussed options for treatment, had given advice about an increased risk of sepsis, and that she had obtained the deceased's informed consent, although this was not fully documented.

[95] The pursuers had failed to establish that there was a usual and normal practice for a consultant urological surgeon to offer only a CT scan in the circumstances which arose in this case, or that no consultant urological surgeon of ordinary skill and care would have acted as Ms Seaward did. They had failed to establish that Professor McClinton's evidence was unreasonable, irrational or illogical such that it required to be rejected. The pursuers must prove that Ms Seaward was guilty of such a failure as no doctor of ordinary skill would be guilty of if acting with ordinary care. They must prove that there was a usual and normal practice, that Ms Seaward had not adopted that practice and that the course that she adopted was one which no professional person of ordinary skill would have taken if acting with ordinary care: *Hunter* v *Hanley* 1955 SC 200, 206.

[96] The clinician had a duty to take reasonable care to ensure that the patient was aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. Possible treatment options and their risks were matters falling within the expertise of the medical profession: *Montgomery*. If a treatment was reasonable according to the test in *Hunter* it should be discussed with the patient. *AH* v *Greater Glasgow Health Board* 2018 SLT 535, paragraphs 42-45. A material risk was one to

which a reasonable person in the patient's position would be likely to attach significance or one to which the doctor is or should reasonably be aware that the particular patient would be likely to attach significance: *Montgomery*, paragraphs 82, 82, 87. What risks associated with an operation were known to the medical profession was a matter falling within medical expertise; whether the patient should have been told about such risks by reference to whether they were material was a matter for the court to determine, and not subject to the *Bolam* test: *Duce* v *Worcestershire Acute Hospital NHS Trust* [2018] Med LR 499, paragraph 33.

[97] The evidence of the expert witnesses was to be tested by reference to the criteria in *Bolitho*. Where there were competing bodies of opinion it was not for the court to prefer one to the other: *Honisz* v *Lothian Health Board* 2008 SC 235, paragraphs 39-40; *Dineley* v *Lothian Health Board* [2007] CSOH 154, paragraphs 37-40. I should consider whether Professor McClinton had a mistaken or incomplete understanding of the facts, whether there had been a proper assessment of the risks and benefits of the course of action adopted, and whether there was a logical basis for his opinion. It was only in a rare case that the court would be able to discount expert evidence on that basis. I should have regard to the proper role of an expert witness as explained in *Kennedy* v *Cordia (Services) LLP* 2016 SC (UKSC) 59, paragraphs 48, 52-54.

Decision

[98] There is much in this case that is not the subject of dispute. The July X-ray clearly showed a stone. The August X-ray did not. All three clinicians who gave evidence thought the stone had probably passed, and that is why it was not visible on the August X-ray. I am satisfied on the balance of probabilities that it had.

[99] All three clinicians who gave evidence agreed that in those circumstances a course of action open to a clinician reviewing the X-rays immediately before an elective procedure, as Ms Seaward was, and exercising the appropriate skill and care, would have been to obtain a CT scan and postpone the procedure pending the result. It is, likewise, common ground that CT scans are more sensitive than X-rays, and more likely to disclose the presence of a stone, but that they are not 100% accurate, and that, in a small percentage of cases, they will not disclose a stone when it is present.

[100] There was, again, no real dispute that the risk of infection from ureteroscopy generally was in the region of 1 to 2% and that the risk of sepsis generally was in the region of 0.3% (Mr Baird came to refer to a range between 0.3% and 0.5%).

[101] It was also not disputed that the deceased was at higher risk of sepsis than the general population. Parties disputed whether or not there was an increased risk arising from the circumstance that she had had an episode of sepsis in 2011, and whether there was a duty to do any more than provide advice that the procedure carried a risk of sepsis.

[102] There is also a dispute as to what, if anything, actually was discussed between Ms Seaward and the deceased.

Informed consent

[103] In relation to the case on record that Ms Seaward had a duty to obtain the deceased's informed consent to the procedure; that she had a duty to discuss fully with the deceased the options for treatment and the risks or benefits of those options; and that she had a duty to discuss the heightened risk of urosepsis given the deceased's previous history of postoperative sepsis (and ensure that she understood the risk), I did not understand there to be any real dispute as to the law that I should apply. A doctor such as Ms Seaward must

take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment and of any reasonable alternative or variant treatments. A risk is material if in the circumstances of the case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should be reasonably aware that the particular patient would be likely to attach significance to it. *Montgomery*, paragraph 87. Whether a risk is material cannot be reduced to percentages, but will reflect a variety of factors such as those mentioned in *Montgomery*, paragraph 89. A doctor must engage in a dialogue with the aim of ensuring that the patient understands, amongst other things, the anticipated benefits and risks of the proposed treatment and any reasonable alternatives. That duty is not fulfilled by "bombarding the patient with technical information which she cannot reasonably be expected to grasp: *Montgomery*, paragraph 90.

[104] In approaching the informed consent part of the pursuers' case, I have addressed the following questions:

(a) Was there an increased risk of sepsis because of the previous episode?

(b) What matters did Ms Seaward have a duty to discuss with the deceased?

(c) What did Ms Seaward discuss with the deceased?

(d) Did the deceased understand any advice tendered?

Was there an increased risk of sepsis because of the previous episode?

[105] The pursuer has not proved on the balance of probabilities that there was an increased risk of sepsis because of the previous episode of postoperative urosepsis. The only evidence that there was such an increased risk came from Mr Baird. He came to accept that, while it was his opinion that that was the case, there is no evidence in the medical literature to show that there is an increased risk of urosepsis where a patient has had a previous

episode. There is, equally, no evidence in published literature to show that there is not an increased risk of urosepsis in those circumstances. Whether or not there is such an increased risk does not appear to have been the focus of published research. Mr Baird provided no information to indicate upon what basis he had formed the opinion that there was an increased risk. I reject his evidence as to the risk being increased because of the previous episode of postoperative urosepsis.

[106] I did not accept Professor McClinton's evidence, as expressed in his report, which he adopted that the absence of complications in 2012 "proved" that there was no higher risk of sepsis because of the 2011 episode. It does not, on its face, make sense. The absence of complications in 2012, if it proves anything, proves that complications are not inevitable simply because they have occurred before. The circumstance that a given risk has not come to pass does not prove that the risk does not exist. The passage of evidence to which objection was taken regarding the differences between the procedures on the different occasions is not material to my conclusion on this matter.

[107] I accept Professor McClinton's evidence that the deceased was at a higher risk of sepsis than the general population because of her age, her sex, her ASA score, and her history of urinary infection, and that the known risk, because of those factors, increased from about 0.3% to about 0.6 or 0.7%.

What matters did Ms Seaward have a duty to discuss with the deceased?

[108] It is common ground that the alternative to proceeding with ureteroscopy on 23 September 2013 was to postpone so that CT imaging could be obtained. It was a reasonable alternative treatment of the sort contemplated in *Montgomery*. It was

Ms Seaward's duty to tell her what the risks and benefits of that procedure were. It was her duty also to tell the deceased what the risks and benefits were of ureteroscopy.

[109] In relation to ureteroscopy, there is no dispute between the experts that the risks included bleeding, instrumental damage to the ureter, of a second planned procedure, irritation or pain if a stent were required, infection and sepsis. I accept that the existence of a risk of sepsis would have been material to the deceased, particularly given her previous history. As I have already indicated, I have rejected the proposition that there was an increased risk of sepsis because of the previous episode of sepsis, and it follows that I reject the proposition that there was a duty to advise that there was an increased risk for that reason. The risk of sepsis was increased for that applicable more generally because of her age, sex, ASA score and history of urinary tract infections. The pursuers do not make on record a case that the deceased would have regarded an increased risk by reason of those factors as material, or that advice should have been given on that basis. I have, however, considered whether it would have been material for the deceased to know that the risk was 0.6 or 0.7% rather than 0.3% in her case. I am not satisfied that it would have been material to her to know of the increase or those particular figures, given that the overall risk remained at a low level. What would have been important to her in weighing the advantages and disadvantages of the treatment options was knowledge that ureteroscopy carried a risk of sepsis, of which she had prior personal experience.

[110] It would have been material also for her to know that if a stone was present it would be visualised during ureteroscopy. If it was present it could be treated during the procedure. If it was not seen, then its absence would have been determined conclusively.

[111] In relation to the option of postponing the procedure, it would have been material for the deceased to know that Ms Seaward had not been able to see the stone on the August

X-ray, and that she believed it was not present. It would have been material also for her to know that there was a small risk that a stone, if present, would not be shown on the CT scan and that it might be necessary in due course, after some weeks delay, to have a ureteroscopy to exclude the presence of a stone if symptoms persisted.

What did Ms Seaward discuss with the deceased, and did she understand any advice tendered?

[112] I approach Ms Seaward's evidence about the events of 23 September 2013 with caution, given the absence of a contemporaneous record. The absence of a proper record of the consent process is unsatisfactory. Ms Seaward's practice at the time of recording it when dictating the discharge letter would not have provided a record of the discussion made at the time it took place, even had she followed that practice in this case. Because the deceased died, Ms Seaward simply did not make any contemporaneous or near contemporaneous written record of the process. She did not make any written record until she composed the letter dated 25 November 2013, some two months after the procedure.

[113] Although I accept that her memory would have been fresh at the time that she wrote the letter of 25 November 2013, it is a response to a complaint. There is a risk that the author of such a letter may come to produce an account which is fashioned, consciously or unconsciously, with a view to resisting the complaint. In spite of this, I was impressed by her oral evidence. She appeared to be a careful, quietly spoken and slightly diffident individual. She was clearly distressed by the death of the deceased. That would not necessarily enhance her credibility, as it might provide a context for evidence given with a view to justifying her actions, but my impression was of sorrow and regret, rather than defensiveness or self-justification. I formed the view that she was doing her best to tell the

truth in giving her recollection of the discussion with the deceased on 23 September 2013 and that her evidence was generally reliable.

[114] Aspects of her account are, to some extent, supported by other evidence. For example, her account that the deceased was continuing to complain of pain is consistent with Ms McNab's account of the deceased's complaints on the occasion when they spoke on the evening before the procedure. Although Ms McNab's account was of the deceased's complaining of a "niggle in her kidney" at that time, which might suggest discomfort that was not severe, I bear in mind also that she presented to Ms McNab as pale and withdrawn, and as looking unwell. Ms Seaward's account that the deceased wished to proceed with the operation is consistent with Ms McNab's evidence that the deceased wished to get to the bottom of the problem.

[115] I accept that Ms Seaward told the deceased that she thought that the stone had passed, and that it would be in the deceased's best interests to have a CT scan. I accept that she told the deceased that she wanted to cancel the procedure. It is clear that that was the course that Ms Seaward recommended. I accept that she informed the deceased that there was a risk of bleeding, instrumental damage to the ureter, a second planned procedure, irritation or pain if a stent were required, infection and sepsis. I accept that she advised the deceased that there was an increased risk of sepsis. It was her practice to advise patients who had had a urinary tract infection before, or a complicated stone procedure which had involved infection or sepsis, of a high risk of sepsis on a second planned procedure.

[116] The pursuers submitted that I should infer from the evidence of Ms McNab that Ms Seaward did not inform the deceased of the risk of sepsis. Ms McNab's evidence was that the deceased was terrified because of what had happened to her in 2011. It followed that had she been given the information that Ms Seaward said she had, she would not have

consented. The deceased was, on Ms McNab's account, someone who was too reticent to ask a nurse for painkillers. She would not have declined to follow advice to postpone the procedure. Ms McNab's evidence was also relevant to causation, in that it supported the proposition that if the deceased had been properly advised, she would not have consented to the procedure.

[117] I am not prepared to draw the inferences for which the pursuers contend from the evidence of Ms McNab. Ms McNab's evidence was given honestly and in good faith, but it necessarily involved a degree of speculation on her part as to what the deceased would have done in particular circumstances, and I am therefore cautious about relying on it as evidence of what the deceased would in fact have done if given particular advice. I have taken into account also the following. It is common ground that the deceased had a procedure in 2012 without complications. In the first place, she underwent that procedure, notwithstanding the very serious complications that she had in 2011. I do not know what advice, if any, she received about the risks of the 2012 procedure, but the fact is that she did have a ureteroscopy in 2012. In the second, it is likely that the absence of complications on that occasion would have provided at least some comfort to her as she contemplated whether to have a further procedure in 2013. I accept that the deceased, when Ms McNab asked her if she was fit to go into hospital, responded by questioning what choice she had. Ms McNab's own assessment of that comment, however, was that the deceased had had infection after infection, and wanted to get to the bottom of the problem.

[118] I do not infer from the fact that the deceased consented to the procedure that she had not been told of the risk of sepsis, and offered the opportunity to postpone it and have a CT scan in the first instance. I do not infer that she did not understand the advice tendered. I accept the evidence of Ms McNab that the deceased wanted to try to find out what was

causing her recurrent infections and pain. Against that background (and leaving out of account for this purpose my finding as to what Ms McNab did discuss with the deceased) it is at least as likely that she would have consented to a ureteroscopy on the view that it could be of some diagnostic benefit, as that she would have chosen to delay the procedure in order to have a CT scan.

[119] It follows that I also reject the case made by the pursuers in relation to causation, so far as the informed consent case is concerned.

[120] The pursuers made in submissions a case that the deceased should have been advised, in her best interests, not to have the procedure, but to have a CT scan. They submitted that the question was what she would have done had she been given that advice. I observe, first, that that is not the case on record relative to informed consent. The pursuers plead that there is no record of any discussion with the deceased preoperatively, or of any discussion with her of risks associated with the ureteroscopic surgery, and in particular the risks of urosepsis. They aver that Ms Seaward had a duty to discuss the heightened risk of urosepsis given the deceased's previous history of postoperative sepsis. They plead, also, that had the risks associated with the ureteroscopic surgery, and in particular the risk of urosepsis, been explained to the deceased, it is unlikely that the deceased would have consented to the surgery. As it is not the case made on record, I do not require to consider it. I am, however, satisfied that, as a matter of fact Ms Seaward told the deceased that it was in her best interests to have a CT scan.

[121] I accepted Ms Seaward's evidence that she was satisfied that the deceased understood the advice given to her. I accepted her evidence that the deceased was distressed when Ms Seaward said she wanted to cancel the procedure. I accepted her evidence that she frequently dealt with people who were distressed at the time of the

discussions relevant to informed consent. The deceased was someone who had previously experienced sepsis, and who would have understood a reference to it, and that a risk of sepsis amounted to a risk of serious and potentially fatal harm. I am satisfied that the deceased was advised in the terms spoken to by Ms Seaward, that she understood the advice, and that she still wished to have the procedure.

Informed consent – conclusion

[122] I am satisfied that Ms Seaward advised the deceased of the risks and benefits of the options of having a CT scan and of proceeding with the ureteroscopy in such a way as to provide the deceased with sufficient information for her to give or withhold consent on an informed basis. I accept that she told the deceased that to have a CT scan would be in her best interests, and that she told the deceased that she wanted to cancel the procedure. It is not clear to me from Ms Seaward's evidence whether the potential disadvantages of having the CT scan (that is, the potential need to have a ureteroscopy if the CT scan were inconclusive and pain persisted) were fully discussed with the deceased. Any failure to explain fully the disadvantages of the CT scan is immaterial in the context of this case. Further information about those disadvantages must have tended to influence the deceased towards the course that she in fact took. I accept that Ms Seaward explained the risks and benefits of ureteroscopy in the way she described in her evidence, including (unnecessarily) an increased risk of urosepsis, and that the deceased chose to have the ureteroscopy. It follows that the pursuers have not made out their case so far as based on failure to obtain informed consent.

Failure to confirm presence of stone by imaging, and failure to cancel the procedure

[123] Again, I did not understand parties to be at odds as to the law I ought to apply. It is for the pursuers to prove that there was a usual and normal practice, that Ms Seaward did not adopt that practice, and that she adopted a course that no professional person of ordinary skill would have taken if acting with ordinary care. It is, however, open to me to find that a person who followed a normal practice was negligent, if that normal practice is one which does not withstand rational scrutiny.

[124] The evidence material to this matter is that of Mr Baird and Professor McClinton. This is a case in which there are competing bodies of opinion as to usual and normal practice. Professor McClinton is a specialist in endourology, with an impressive record of publication relating to urolithiasis specifically. His clinical practice included very many procedures for stones every year. He is well qualified to provide evidence about normal practice in the field of endourology in general and stone surgery in particular. I did not consider that he had become an advocate in the way that Mr Clarke contended. I agree with Mr Clarke that, as a reasonably experienced expert witness, Professor McClinton ought to have avoided volunteering evidence in relation to a line which had been the subject of objection. Looking at his evidence in the round, however, my impression was that he sought to provide a genuine and honest opinion as to practice in the relevant area. Although I did not accept his analysis regarding the absence of increased risk in the terms in which he proffered it, I regarded him otherwise as a credible and reliable witness as to the usual and normal practice of a responsible body of urological surgeons at the material time. There was no material difference between Mr Baird and Professor McClinton as to their understanding of the deceased's history and presentation, or as to what was disclosed in the July and August CT scans.

[125] I am satisfied that Ms Seaward was not negligent in carrying out the procedure on 23 September 2013 without first having obtained a CT scan, or in respect that she did not cancel the operation, or postpone it until a CT scan was available. I accept the evidence of Professor McClinton that a reasonable body of clinicians would have acted as Ms Seaward did in the circumstances, namely where she suspected that the stone had cleared, but the deceased continued to complain of pain. A reasonable body of clinicians would not have insisted on further imaging by way of CT scan before proceeding. There is no proper basis in Mr Baird's evidence for concluding that the course adopted by Ms Seaward, and supported by the evidence of Professor McClinton, does not withstand rational analysis. I say that for the following reasons.

[126] Mr Baird's evidence was that the only safe course, taking into account the deceased's previous medical history, was to obtain a CT scan before proceeding, and to refuse to carry out the procedure on 23 September 2013. The course adopted by Ms Seaward was, he said, a highly risky course. During his evidence in chief he agreed that some clinicians would proceed with a ureteroscopy in the circumstances of the present case, but said that to do so would be the "wrong approach", especially in a patient at "high risk of complications".

[127] Mr Baird's view that the course adopted by Ms Seaward was a highly risky one was informed at least to some extent by his opinion that the risk of sepsis, so far as the deceased was concerned, required to be multiplied several times compared with that relating to patients who did not have a previous history of post-operative sepsis. As I have already mentioned, he did not provide any information as to the basis on which he had formed that opinion. It was, as he accepted, not supported by published research, and I rejected it. His objections to the course followed by Ms Seaward focused on "the particular patient" and his

view of the risk arising from her previous medical history, particularly, but not exclusively, of the previous episode of postoperative urosepsis.

[128] He was also of the view that it was "guaranteed" that any stone present on 23 September 2013 would have shown on a CT scan, simply because the same stone had previously been clearly visible on an X-ray. There can be no guarantee that the stone would have been shown, even where, as I understood it, both Professor McClinton and Mr Baird would have expected it to be shown had it been present.

[129] Professor McClinton provided in his evidence a logical basis for proceeding to a ureteroscopy. It is a procedure which would demonstrate conclusively whether there was a stone present. The context was one of a patient still complaining of pain which she said was the same as that she had experienced from a stone. The context also was one in which, on the available published evidence, the risk of sepsis is a small one, even in someone of the deceased's age and sex with an ASA score of 3.

Failure to obtain and check urine cultures

[130] The case insofar as based on a failure to obtain a urine culture fails. The pursuers advanced no case on causation in evidence (or averment) as to what the result of such investigations would have been, or what the response to such a result would have been. That is sufficient to dispose of this aspect of the case. I record, however, that I accepted the evidence of Professor McClinton that there was a practice at the material time, followed by a reasonable body of practitioners, of carrying out a dipstick test on the morning of the procedure. I accept that the European Association of Urology guidelines specified that microscopy or a urine culture should be mandatory "before any treatment is planned". I accept, also, in general terms, that microscopy or a urine culture will disclose more

information than will a dipstick test. The distinction between these investigations, and what each would respectively disclose was not, however the subject of detailed exploration in evidence. I am unable in those circumstances to take the view that the practice of which Professor McClinton gave evidence was one which would not stand rational scrutiny. The evidence led at proof does not provide a basis for that conclusion.

Disposal

[131] I repel the first and second pleas in law for the pursuers; sustain the second and third pleas in law for the defenders and therefore assoilzie the defenders from the conclusions of the summons.