Case No: KB-2022-BHM-000161

IN THE HIGH COURT OF JUSTICE KING'S BENCH DIVISION BIRMINGHAM DISTRICT REGISTRY

Birmingham Civil and Family Justice <u>The Priory Courts</u> <u>33 Bull Street</u> Birmingham B4 6DS

Date: 12 December 2024

Before:

HER HONOUR JUDGE EMMA KELLY (Sitting as a Judge of the High Court)

 $Between\colon$

MJF

(A Protected Party proceeding by her mother and litigation friend, ITZ)

Claimant

- and –

University Hospitals Birmingham NHS Foundation Trust

Defendant

Benjamin Bradley (instructed by Irwin Mitchell LLP) for the Claimant Matthew Barnes (instructed by Bevan Brittan LLP) for the Defendant

Hearing dates: 16th, 17th, 18th, 19th, 20th, 23rd September 2024

Approved Judgment

Her Honour Judge Emma Kelly:

- 1. This is the judgment upon the issue of liability only in this clinical negligence claim.
- 2. MJF ('the claimant') seeks damages for personal injuries and associated losses said to arise from the alleged negligent performance of surgery to insert a Percutaneous Endoscopic Gastrostomy ('PEG') feeding tube on 22 March 2016. The surgery was performed at Good Hope Hospital in Sutton Coldfield, which is part of University Hospitals Birmingham NHS Foundation Trust ('the defendant').
- 3. It is an unfortunate feature of this claim that little thought was given to which documents should be included in the trial bundle. Although the key documents were presented in two lever-arch files, the court was presented with a further 27 files containing medical records, the vast majority of which were never referred to. I am grateful to the defendant's legal representatives for producing an additional file containing key medical records. The court has also been assisted by helpful skeleton arguments and skeleton written closing submissions from counsel. The parties arranged for same-day transcription of the hearing such that the court has the benefit of transcripts of all of the evidence.

Background

- 4. The claimant was born on 3 October 1991. She has a complex medical history with congenital cerebral palsy, autism, and epilepsy.
- 5. Following concerns as to the claimant's oral intake, the claimant was referred for gastroenterological review which led to a decision to proceed with a PEG.
- 6. At around 11 am on 22 March 2016, the claimant (then aged 24) underwent the PEG insertion at Good Hope Hospital under sedation. Dr Mark Andrew, a Consultant Gastroenterologist, performed the procedure, assisted by Ms Sinead McCann, a Nurse Endoscopist.
- 7. The claimant was discharged home at around 1 pm the same day and the first feed was delivered via the PEG tube later that evening.
- 8. At around 5 am on 24 March 2016, a carer found the claimant unresponsive on the floor. The claimant was taken to Queen's Hospital in Burton on Trent by ambulance. An emergency laparotomy was performed with the operation note recording:

"Four quadrant peritonitis with feed solution within the abdominal cavity (no faeces). Necrosis around gastrostomy site due to position of PEG being too high (positioned almost to fundus) resulting in tension at the gastrostomy site...."

HHJ Emma Kelly

[2024] EWHC 3156 (KB) . The claimant experienced acute respiratory distress syndrome, sepsis, and multi-9. organ failure requiring ventilation. She remained in intensive care for four

months and thereafter remained an inpatient until her discharge from hospital on 22 May 2017.

 It is not in dispute that the claimant's level of functioning deteriorated significantly following the events on 24 March 2016.

Summary of the claimant's case

- 11. As the experts refined their reports, both parties amended their pleaded cases. The Amended Particulars of Claim plead the claimant's case as to breach of duty as follows:
 - Insertion of the PEG with too much tension between the internal bumper (inside the stomach) and the external bumper (on the surface of the skin);
 - ii) Failure to insert the PEG so that the external bumper had a centimetre or two of play between its position on the line and the surface of the skin;
 - iii) Failure to detect that the PEG was under too much tension and correct the same before concluding the operation.
- 12. The plastic devices attached to the external and internal ends of the feeding tube are referred to by the witnesses in this case as variously 'bumpers', 'flanges', or 'fixation devices'. The words are used interchangeably and have the same meaning.
- 13. The claimant no longer alleges that the PEG was positioned too high in the stomach.
- 14. The claimant's case on causation is that the tension between the internal and external bumpers prevented blood supply to the stomach wall at the site of the PEG, causing the tissue to die, and thus allowing the contents of the stomach to escape into the abdominal cavity causing peritonitis and sepsis with a hypoxic episode.
- 15. The claimant asserts that this resulted in a significant worsening of her underlying neurological condition. She claims that before the procedure, she lived in a cottage adjacent to her parents' home with the support of a single 24- hour carer providing sleeping night-time support. Her case is that she was mobile, continent, and able to communicate her needs via limited Makaton sign language. She alleges that the complications of the procedure have resulted in her requiring a wholly different regime of care with two 24-hour carers, and waking night-time care. The claimant's case is that she is now unable to walk, weight bear or sit up, is doubly incontinent, has a tracheostomy, and is fed via a PEG feeding tube.

Summary of the defendant's case

- 16. The defendant denies any breach of duty and asserts:
 - i) Reasonable care was taken to site the PEG in an appropriate position in the

HHJ Emma Kelly [2024] EWHC 3156 (KB) body of the stomach;

- Reasonable care was taken to place the external bumper at 2.5 cm from the internal bumper, with approximately 1.5 cm excess over the 1 cm between the surface of the abdomen and the stomach;
- iii) After the external bumper was placed, the PEG was manipulated to ensure that the distance between the bumpers was not too tight and there was no tension on the PEG.
- 17. The defendant denies that the breakdown of the tissues surrounding the PEG was caused by pressure between the internal and external bumpers. The Amended Defence asserts that the breakdown of tissue occurred despite the exercise of reasonable care and skill. In other words, this was simply a rare, but recognised, complication of the procedure.
- 18. The defendant's original Defence alleged that the tissue breakdown was likely to have been caused or contributed to by variously, the manipulation of the PEG by the claimant when she was awake; pressure placed on the PEG by the claimant when she was either awake or asleep, or when she fell from her bed to the floor; or by poor wound healing caused or contributed to by the claimant's condition, nutritional status or use of naproxen. Those theories were abandoned by an amendment to the Defence on 6 September 2024.
- 19. Whilst the defendant accepts that the claimant suffered a deterioration in her condition as a result of the complications, it asserts that any causative impact is limited to a six-year acceleration of a pre-existing deterioration in the claimant's condition.

Issues

20. The issues for determination can be summarised as follows:

Standard of care and breach of duty

Issue 1: Whether the PEG was placed with too much tension between the internal and external bumpers in breach of the duty of care owed by the defendant.

Causation

Issue 2: If so, whether the tension prevented the supply of blood to the stomach wall causing the tissue to die resulting in peritonitis and sepsis.

Acceleration

Issue 3: If so, whether the admitted deterioration in the claimant's condition is wholly caused by the negligence or whether it accelerated an inevitable deterioration in the claimant's condition by a period of six years.

HHJ Emma Kelly [2024] EWHC 3156 (KB) 21. There are two key factual disputes between the parties.

- i) Whether the skin to gastric lumen distance on 22 March 2016 was 2.5 cm, as contended for by the claimant, or 1 cm, as contended by the defendant.
- Whether the claimant's level of functioning was already deteriorating in the period before 22 March 2016, and in particular, in respect of her mobility, continence, and swallow function.

The lay witness evidence

The claimant's lay evidence

- 22. The claimant relies on the following lay witnesses:
 - i) The claimant's father.
 - ii) The claimant's mother.
 - iii) Molly Evans, a carer who worked with the claimant for approximately four years between 2012 and 2016.
 - iv) Lois Evans, a carer who worked with the claimant from approximately 2011 to 2020.
 - v) Tracy Sheasby, a carer who has worked with the claimant for nearly 26 years and continues to do so.
- 23. An anonymity order has been made in this case. To preserve the claimant's anonymity, this judgment will refer to the claimant's parents as 'the claimant's father' or 'the father' and 'the claimant's mother' or 'the mother' rather than their names. No disrespect is intended.
- 24. Each of the claimant's lay witnesses gave oral evidence addressing events around the date of the PEG procedure, and the claimant's level of functioning before and after the surgery. It is clear that the claimant's parents have provided decades of dedicated care and support to further the welfare of the claimant and her disabled sister, and have been assisted by a very loyal team of carers.

The claimant's father

25. The father's written evidence described the claimant's level of functioning before the procedure on 22 March 2016. He explained that, even before the procedure, the claimant lacked capacity and required 24-hour care. However, he stated that her communication skills were adequate for her needs and, although she required a wheelchair for longer distances, she was able to move around her cottage and climb stairs. He described the claimant beginning to suffer episodes of vomiting in 2015 but that no medical reason was found for vomiting or reflux. He understood that the PEG was to be fitted to help 'top up' the claimant's fluids.

HHJ Emma Kelly

12024] EWHC 3156 (KB)
26. The father attended the hospital with the claimant on 22 March. Following the procedure, he stated that he could see right away she was not well and was

hunched over. He described her remaining unwell the next day and the GP prescribing naproxen, which the claimant started to take.

- 27. He explained that, following the claimant's emergency admission to hospital on 24 March 2016, she underwent surgery leading to an extended stay in the intensive care unit before transfer to a high dependency unit. He stated that the claimant deteriorated during her 14-month hospital stay such that she lost all mobility, was unable to feed herself, needed a tracheostomy, and was now dependent on two specialist support workers 24 hours per day.
- 28. The father was cross-examined about striking similarities between his witness statement and that of his wife, with multiple passages drafted in identical terms. He told the court that the wording reflected the joint words of himself and his wife. He accepted that some parts of his statement also mirrored parts of the statement of Tracy Sheasby. He told the court that the statements had been typed for them but that they nonetheless reflected the truth.
- He was asked about the claimant's level of functioning before the PEG procedure. 29. He explained he was not involved in the claimant's care on a day-to- day basis but that he was aware that the claimant had been able to walk on her own within her cottage and from the cottage to the carer's car, a distance of some 30 to 40 yards, and was able to climb into the car. She would use a wheelchair for longer distances, and on occasions such as going to a hospital appointment, when it was more convenient to do so. He accepted that the claimant often walked holding the hand of another but considered that was more because she was autistic and liked the routine, rather than because there was a physical need for such assistance. He described the claimant as a mobile and independent young woman in the period leading up to the procedure. He did not accept there had been any deterioration in her mobility in the years leading up to March 2016. When he was taken to a series of medical records over the years leading to 2016, he said he did not recognise the description of the claimant's mobility difficulties as documented in some of the notes. He did not accept any deterioration in the claimant's mobility was as severe as the defendant suggested.
- 30. The father understood the claimant to be toilet trained before the procedure but did not get involved in her personal care. It became clear that much of his knowledge on continence issues was based on what he had been told by others. His understanding was that the claimant had been able to communicate when she wanted to use the toilet, could walk to the toilet, possibly holding someone's hand, and the carers would clear up afterwards. He did not believe the claimant's level of continence had changed much over the years leading to 2016.
- 31. The father was asked about the claimant's ability to swallow, and her eating and drinking ability in general. He stated he did not get involved in feeding; but did not consider that there was really a problem until the claimant started to have difficulties taking in enough fluid.

HHJ Emma Kelly

[2024] EWHC 3156 (KB)
 32. Overall, he did not accept that the medical notes reflected his recollection of his day-to-day experience of the claimant's level of functioning in the period prior to March 2016.

The claimant's mother

- 33. The mother's witness statement is in nearly identical terms to that of her husband. When cross-examined about the obvious similarities of the statements, she was somewhat defensive. She told the court the words were definitely her and her husband's own words because they wrote the statements separately. When it was put to her that could not possibly be correct given the identical wording, she conceded there may have been an element of one person writing it first and the other agreeing. She also accepted that she would have discussed the evidence with Mrs Sheasby, but maintained that Mrs Sheasby wrote her own statement.
- 34. The mother told the court there was no deterioration in the claimant's mobility between the time she learned to walk, at around 3½ years old, and March 2016. She stated there was similarly no deterioration in continence from the point that the claimant was toilet trained to March 2016. She accepted that there could be short-term issues with incontinence if the claimant had a seizure, but that she thereafter regained functionality to her previous level. She told the court that the purpose of the PEG was not because of difficulties with swallowing, but because the claimant did not like to drink.
- 35. The mother was taken to a series of entries in the claimant's medical records across the years prior to the procedure. As with her husband, she did not accept that all of the descriptions in the medical records were an accurate reflection of the claimant's level of mobility, continence, and swallowing ability.

Ms Molly Evans

- 36. Ms Molly Evans was a carer for the claimant for approximately four years from 2012 to 2016. She predominantly worked night shifts but also Sunday day shifts. In her written evidence, she described the claimant's level of functioning before the procedure in positive terms; whilst the claimant had been non-verbal, she had good Makaton communication skills and could walk around unaided, often getting in and out of bed and taking herself to the toilet.
- 37. On 23 March 2016 Ms Evans worked the night shift from 5 pm. At around 5 am on 24 March 2016, she found the claimant on the floor and struggling to breathe.
- 38. In cross-examination, Ms Evans was taken to a series of entries in the claimant's medical records. Unlike the claimant's parents, she was far more accepting that the documented descriptions in the medical records of the claimant's abilities regarding mobility, continence, and swallowing were accurate. She explained that the claimant had 'good days' and 'bad days' but that there was no consistent deterioration. She stated that the claimant had help with transfers out of bed, but could do it herself, if needed. She agreed that the claimant mobilised very short distances in the house holding someone's hand. She described the claimant as being able to take herself to

[2024] EWHC 3156 (KB) the toilet during the day and wearing a pad at night. She agreed that the claimant's swallowing ability deteriorated over the time she had cared for the claimant.

Ms Lois Evans

- 39. Ms Lois Evans was a carer for the claimant for 11 years from 2011 to 2020, save for a short break of around six months in 2019. She worked predominantly night shifts. In her written evidence, she described the claimant in the period before the procedure as being non-verbal but having good Makaton communication skills to communicate basic needs such as needing the toilet, feeling tired, wanting to go to bed, and feeling hungry or thirsty. She stated that the claimant was able to do a lot of tasks herself. She saw her role as a carer as someone to provide company and support with walking and feeding. She said the claimant was able to walk by herself but held onto furniture or the carer's hand.
- 40. In cross-examination, Ms Evans told the court that she wouldn't describe the claimant as deteriorating between 2011 and 2016 but maybe having 'slowed down a little bit'. By that, she said she meant that the claimant was less interested in doing things unless she was really encouraged.
- 41. Ms Evans was taken to a series of entries in the medical records. She said she didn't recall thinking that the claimant was deteriorating and did not recall a time when the claimant started to fall. Her impression was that the claimant was just less willing to walk. She did accept there was maybe a little deterioration in continence over the period before the procedure. She also agreed that there had been a deterioration in the claimant's ability to eat food and drink fluids.

Mrs Tracy Sheasby

- 42. Mrs Sheasby has worked with the claimant for nearly 26 years. Her written evidence described the claimant prior to the procedure as being able to communicate her needs, walk unaided, get in and out of bed unaided, take a good part in getting dressed, get on and off a chair unaided, and take herself to the toilet independently. She stated the claimant was also able to walk to the car, get in and out of the car independently, and only required a wheelchair for longer distances.
- 43. Mrs Sheasby's witness statement provided an account of the claimant's typical daily routine before the PEG procedure. This involved the claimant getting herself out of bed to use the toilet, communicating what she wanted for breakfast using Makaton, and taking her tablets with a drink. The claimant got washed and dressed, mostly by herself, but with some assistance brushing her hair and applying cream. Ms Sheasby described the claimant as able to brush her teeth and help with cleaning up breakfast dishes and vacuuming the lounge. She described often taking the claimant out for lunch or to meet the claimant's friends. The claimant ate something for lunch such as a jacket potato with cheese and baked beans, or a sandwich and some soup. The claimant would take a short walk after lunch. Mrs Sheasby described herself and the claimant preparing dinner, which could be cottage pie with mashed-up peas and carrots. The claimant would then get ready for bed, mostly by herself, but with some

HHJ Emma Kelly [2024] EWHC 3156 (KB) additional support.

- 44. In cross-examination, Mrs Sheasby stated she had no idea why the wording of part of her statement was identical to that of the claimant's parents. She accepted that she and the parents had discussed what they would say in their witness statements, but said she had never seen their statements.
- 45. Mrs Sheasby was cross-examined about her written account of the claimant's typical routine and she confirmed it reflected the position immediately prior to the PEG procedure. She accepted that the claimant had slowed down somewhat in terms of mobility, but did not accept there was any big deterioration in the claimant's level of continence and described the position 'as going up and down'.
- 46. Mrs Sheasby was taken through various medical records and, rather like the claimant's parents, did not recall the claimant suffering from the issues documented by medical professionals. She did however agree that medical records portrayed a picture of the claimant having deteriorated between 1998 and 2016 but stated that she never noticed a time where she thought *'oh god, she can't do this, she can't do that'*. When taken to the medical records relating to continence, she agreed that the bowel position had changed over the years and progressed to the use of a bowel irrigation system. She did not accept there was a deterioration in respect of bladder function, other than occasional wetting, and stated it had never reached a position where pads had to be worn constantly. Mrs Sheasby accepted that the claimant's swallowing deteriorated in around 2014/15 but that she recollected that the issue was with drinking rather than eating.

The Defendant's lay evidence

- 47. The defendant relies on the lay evidence of:
 - i) Dr Mark Andrew, the consultant gastroenterologist performing the PEG procedure.
 - ii) Sinead McCann, the nurse endoscopist assisting in the PEG procedure. Dr

Mark Andrew

- 48. In his first witness statement, Dr Andrew stated that he had a very good memory of the claimant and the procedure; and that his witness statement was based in part on his usual practice, in part on what he could remember, and in part on the medical records.
- 49. He noted that the medical records recorded the procedure commencing at 10.45. He exhibited a copy of the endoscopy report to his statement. The material extract from the report follows:

- 50. In his written evidence, Dr Andrew described the process by which Nurse McCann passed the endoscope camera through the claimant's mouth and into her stomach. The inside of the stomach was illuminated by the light on the endoscope and inflated with air. He explained that he identified the desired incision spot on the exterior abdominal surface by noting where the light was brightest, this being where the stomach was closest to the abdominal wall. He also pressed the abdomen with his finger in different places to check, via the endoscope camera, where the largest indentation was made. He described then puncturing the stomach with a standard 21-gauge green needle until he had aspirated air. He recalled that the claimant's abdominal wall was very thin such that he was able to aspirate air after the needle had passed into her abdomen to a depth of about 1 cm. Dr Andrew thus concluded that the distance between the claimant's skin surface and stomach was only about 1 cm.
- 51. Dr Andrew described how he then inserted a trocar in the same direction as the tract made by the green needle; and passed a wire through the trocar, which was caught by the snare on the endoscope and pulled back through the mouth. The feeding tube was attached to the wire and pulled back through the mouth into the claimant's stomach until it was pulled through the stomach wall. Dr Andrew described fitting the external bumper at 2.5 cm. His statement reads *'this means there was a distance of 1.5 cm between the external bumper and the skin surface. I was confident of this because the depth of the abdomen wall and stomach had already been assessed to be around 1 cm'.* Dr Andrew stated that he checked that the bumper had some 'play' and that there was no tension before the claimant left the procedure room.
- 52. In his first witness statement, Dr Andrew accepted that his entry in the endoscopy report of 'skin-gastric lumen distance 2.5 cm' was incorrect and he meant that the flange to gastric lumen distance was 2.5 cm. He attributed the error to how Endobase reporting software operated. He explained that the software had a series of drop-down boxes into which he had to input various data and that the pre-set description

on one of the boxes was 'skin-gastric lumen distance' rather than the appropriate wording which would have been 'flange- gastric lumen distance'.

- 53. Dr Andrew made a second witness statement, clarifying how he had assessed the measurements he had provided. He explained that he did not formally measure the skin-to-gastric lumen distance and that the only dimension that was specifically 'measured' during the procedure was the point at which the external bumper was fixed on the PEG tube. He explained that the PEG tube had markings at 2 cm intervals and he used those markings to estimate that the external bumper was fixed at 2.5 cm, as it fell between the 2 cm and 4 cm markings. He stated he fixed the external bumper by gently pulling the PEG tube until slight resistance was felt from the internal bumper resting against the stomach wall. He then fixed the external bumper so that it lay comfortably against the external skin surface without tension. He explained that the correct placement is achieved by feel not measurement.
- 54. Dr Andrew produced an unopened Freka PEG set of the type used in the procedure. The set included a written instruction booklet. Dr Andrew demonstrated to the court the various components and explained how the PEG is fitted to a patient. The court has also been provided with an instruction video produced by the manufacturers of the Freka device.
- In cross-examination, Dr Andrew provided further detail as to how the endoscopy 55. reporting software operated. He stated that the drop-down box for 'skin-gastric lumen distance' was pre-set to 4 cm and the onus was on the medical professional to change the distance. It was put to Dr Andrew that if he had, as he said in his statement, estimated the skin-to-gastric lumen distance as 1 cm, he would have recorded the distance as 1 cm not 2.5 cm in answer to the 'skin-gastric lumen distance' question. Dr Andrew did not accept that proposition. He explained that, at the time, the defendant was pursuing national accreditation and was only permitted to use certain software that was compliant with the National Endoscopy Database, notwithstanding that it was known that the software contained typographical errors. He stated that he used a workaround to correct the error by adding details to a free text box, seen on the endoscopy report under the heading 'Aftercare and Treatment', to record the flange to gastric lumen distance at 2.5 cm. He admitted that the effect of his evidence was that he was making regular inaccurate entries in medical records as to skin-to-gastric lumen distances. He accepted that his approach did not tell the reader of the endoscopy report that the entry recording the skin-to-gastric lumen distance at 2.5 cm was incorrect.
- 56. Dr Andrew agreed that one must avoid tension when fitting a PEG, but maintained that there was no tension in the claimant's case and he had left between 1 and 2 cm of play. He admitted that it was only some seven years after the procedure that the defendant had first asserted a positive case that the abdominal wall had an estimated depth of 1 cm and that 1 to 2 cm of play had been left. He also agreed that the time stamps on photographs taken by the endoscope were incorrect by an hour and the overall PEG procedure took approximately 15 minutes.

HHJ Emma Kelly [2024] EWHC 3156 (KB)

57. Later in cross-examination, Dr Andrew suggested he would not have known that the drop-down box for the 'skin-gastric lumen distance' had the wrong label until the endoscopy report was printed. By that stage, it would not have been possible to go back and edit the text as the software system was locked.

58. In re-examination, Dr Andrew stated that the skin-to-gastric lumen measurement has no clinical significance. He explained that the skin-to-gastric lumen distance will be smaller when the stomach is under inflation during the procedure, than when the stomach has deflated at the end of the PEG insertion. He told the court that if he had been able to measure the skin-to-gastric lumen distance at the end of the claimant's procedure, he would have expected it to be roughly 2.5 cm. I was puzzled by that answer given that such an assessment would mean that, on one interpretation, his recording in the endoscopy report of skin-to-gastric lumen distance at 2.5 cm was accurate. That was at odds with Dr Andrew's detailed written and earlier oral evidence explaining that the recording in the endoscopy report of the skin-to-gastric lumen distance at 2.5 cm was inaccurate. In answer to a question of clarification I asked, Dr Andrew confirmed his evidence that the post-procedure skin-to-gastric lumen distance would have been roughly 2.5 cm. When I asked why it was he was therefore contending that the endoscopy report was inaccurate, he did not directly answer the question but stated that he believed the only accurate recording of a measurement on the endoscopy report was the recording of the external flange being fixed at 2.5 cm.

Nurse McCann

59. Mr Bradley did not cross-examine Nurse McCann and her evidence proceeded in written form. Nurse McCann details her role in operating the endoscope and describes the general procedure by which the PEG was inserted. She does not comment on the skin-to-gastric lumen distance or whether the PEG was inserted under tension.

The expert evidence

- 60. Each party relies on expert evidence in the following fields:
 - General surgery: Mr Abeezar Sarela for the claimant (report dated January 2024) and Mr Andrew Wyman for the defendant (report dated February 2024).
 - Gastroenterology: Professor Ian Gilmore for the claimant (report dated January 2024) and Dr George Bird for the defendant (report dated February 2024).
 - iii) Neurology/Neurorehabilitation: Dr Ganesh Bavikatte, Consultant in Neuro-Rehabilitation Medicine, for the claimant (report dated January 2024) and Dr John Bowler, Consultant Neurologist, for the defendant (report dated February 2024).
- 61. Each discipline of experts provided a joint statement and attended court to give oral evidence.

The general surgeon experts

- 62. The joint statement of Mr Sarela and Mr Wyman of 16 May 2024 reveals several areas of agreement:
 - i) The insertion of a PEG would inevitably place some tension on the stomach wall. However, in most cases, this tension is clinically insignificant.
 - ii) Excessive tension between the internal and external bumpers is a possible cause of necrosis at the PEG entry site.
 - iii) Leakage of gastric contents from the PEG entry site was a complication that was inherent to a PEG insertion procedure, despite the exercise of due care and skill. Necrosis of the stomach wall around the PEG site is one possible cause of such leakage.
 - iv) If the court finds that the skin-to-gastric lumen distance was I cm, then the necrosis of the claimant's stomach wall around the PEG site was the manifestation of a 'recognised' risk.
 - v) On 24 March 2016 the claimant had necrosis of the stomach wall at the entry site of the PEG tube.

Likely skin-to-gastric lumen distance on 22 March 2016

- 63. Mr Sarela and Mr Wyman disagreed in their joint statement as to the likelihood of the claimant's skin-to-gastric lumen distance being 1 cm (as contended for by the defendant) or 2.5 cm (as contended for by the claimant). Mr Sarela opined that, on the balance of probabilities, the distance would have been 2.5 cm, whereas Mr Wyman concluded it was 1 cm.
- 64. Mr Sarela justified his position in the joint statement by reference to two factors he had explained in greater depth in his original report.
 - i) He asserted (at para. 5.19 5.25 of his report) that the average skin-to-gastric lumen distance, based on data from different studies, was 2.6 cm (using data from a study by Chaves et al.) or 3.5 cm (using data from a study by Kim et al.). When calculating the average distances, he added to the data from the Kim and Chaves studies to data as to the mean thickness of the gastric wall of the distal body. He took this latter measurement from a study by Abu Ghanem et al., which found the mean thickness of the gastric wall was 2.2 mm. Mr Sarela concluded that a skin-to-gastric lumen distance of 1 cm was a possibility, but represented a point towards the extreme low end of the spectrum. He did not believe the claimant's then body mass index of around 20 placed her at the extreme end of leanness such that a distance of 1 cm was likely.

HHJ Emma Kelly

 [2024] EWHC 3156 (KB)
 ii) He further opined (at para. 5.26 – 5.28 of his report) that the position of the claimant's current PEG supports the proposition that the skin-to- gastric lumen distance on 22 March 2016 would have been 2.5 cm. The

claimant's present feeding tube is set at 2.7 cm. He acknowledged the present feeding tube is not located at the same site as the original PEG but concluded that the different location was only likely to account for a few millimetres of change. Any scarring at the PEG site was very unlikely to increase the distance by more than a few millimetres.

- 65. Mr Sarela's conclusions as to the likely skin-to-gastric lumen distance were explored in cross-examination. He accepted that the Abu Ghanem study was conducted in the context of bariatric surgery, involving a group of individuals who were very substantially heavier than the claimant and that 1.3 mm (rather than 2.2 mm) was a more suitable starting point for determining the likely thickness of the claimant's gastric wall.
- 66. He agreed one could only safely consider the data from the Chaves study concerning the 10 underweight and 10 normal-weight individuals in that study. Whilst the study was small, he noted that the paper's authors had conducted a power calculation to substantiate the reliability of the figures. He agreed that the data was consistent with one in 10 patients having an abdominal thickness of 1 cm.
- 67. Mr Sarela accepted that the abdominal muscle thickness measurement points taken by the authors of the Kim study at the xiphoid and umbilicus levels were not the same locations as the claimant's PEG. He stated that one would have to take a point between the xiphoid and umbilicus to mirror the position of the claimant's PEG but that it was not possible to say which of the points was a closer match. He accepted that the authors of the Kim study had only measured the subcutaneous fat depth at the umbilicus level and that there was no data as to the fat depth at the xiphoid level. He did not however accept that it was unsafe to adopt the fat depth data at the umbilicus level as he would not expect to see a significant difference in the fat measurements in the different locations within the abdominal wall.
- 68. Mr Sarela's reliance on the length of the current feeding tube was also challenged. Mr Sarela agreed that the current MIC-KEY PEG was fitted to a now matured stoma and, as such, although it will not be fitted with tension, it will be fitted with a redundancy of 1–1.5 cm of play. He explained that the current feeding tube indicates that the distance between the claimant's skin surface and the inner lining of the stomach is between 2.5 and 2.7 cm. He accepted the current PEG was in a different location to the original but opined that any difference in thickness of the skin-to-gastric lumen distance would only be a few millimetres, by which he meant between 1 and 3 mm. He agreed infection or granulation could increase the skin-togastric lumen distance but, if treated, would not continue to do so. He noted that the medical records suggested that the claimant had increase abdominal wall thickness by about 10%. He maintained that even factoring in an increase in weight, possible infection, and difference in location of the siting of the PEG, the differences would

HHJ Emma Kelly

[2024] EWHC 3156 (KB) not account for more than a few millimetres. As such, he considered the current length of the stoma a useful guide.

- 69. In the joint report, Mr Wyman justified his opinion that the skin-to-gastric lumen distance was 1 cm by reference to two factors.
 - i) He noted that the range of abdominal measurements in the Chaves study was +/- 1.7 cm such that extrapolating the data to conclude that 2.5 cm is the more likely measurement is unreliable, particularly given that the claimant was at the lower end of the BMI spectrum. He also pointed to another study showing that the average abdominal wall thickness in non- obese individuals was only 1.7 cm.
 - ii) He did not consider that the current skin-to-gastric lumen distance was a reliable indicator of the distance in March 2016: the PEG is in a different part of the stomach and correspondingly a different part of the abdominal wall; the claimant has gained between 7–10 kg of weight since 2016 and will thus have more subcutaneous fat; and longer-term PEG cannulation leads to a buildup of scar tissue, tissue oedema and granulation tissue, all of which can lead to a gradual thickening of the abdominal wall.
- 70. Mr Wyman's position on the skin-to-gastric lumen distance was explored in crossexamination. On being taken to the Chaves study, he interpreted that data as indicating that a person with a BMI of around 20 is likely to have an abdominal wall below 2 cm and it is quite probable it could be 1 cm. He was asked about the oral evidence Dr Andrew gave as to the increase in abdominal wall thickness when the stomach was no longer inflated. Mr Wyman agreed there would be a difference, but told the court that it would be very marginal. He indicated that all the current feeding tube tells us is that the current skin-to-gastric lumen is no more than 2.7 cm but could be less.
- 71. In re-examination Mr Wyman explained that once the initial PEG is inserted and the stomach is no longer under inflation, the outer bumper will fall to the skin's surface. Any slack in the tube will mean that the internal bumper will travel into the stomach lumen. He explained that irritation caused by the presence of the tube stimulates an inflammatory reaction and makes the stomach adhere to the abdominal wall causing scarring and fibrosis around the tube. This results in a mature tract or tunnel between the inside of the stomach and the skin surface.

Cause of the necrosis

- 72. Mr Sarela concluded in the joint report that if the court finds that the skin-to- gastric lumen distance was 2.5 cm, *"then it becomes much more likely that there was excessive tension between the internal and external bumpers*".
- 73. In cross-examination, Mr Sarela accepted that leakage can happen from around a PEG site despite due care and skill. Mr Sarela was taken to a paper by Rahnemai-Azar et al., exhibited to Mr Wyman's report, that identified minor complications of

HHJ Emma Kelly [2024] EWHC 3156 (KB)

a PEG procedure as including local wound infection and periostomal leakage. Mr Sarala accepted that some infections can lead to deterioration and death of tissue. He did not accept that leakage would cause necrosis but rather necrosis would cause leakage. He stated he could not postulate a mechanism by which puncturing the stomach with the trocar and dilating the orifice in the stomach would of itself lead to necrosis of the gastric wall.

- 74. Mr Sarela agreed there is always some tension on the stomach wall because the inside bumper places traction but, in most cases, it is clinically insignificant. He noted that the positioning of the internal and external bumper is important to prevent local site complications, which are more likely if the fit is too tight. He agreed that non-negligent complications can occur but, the tighter the bumper, the greater the risk that complication will eventuate. Mr Sarela agreed that for necrosis to occur within two days, the tension would have to be significant. He stated that the development of necrosis could be a prolonged process or rapid and was not aware of any way of objectively quantifying it. He reported having seen necrosis of the bowel occur within a day or two of an index event. Mr Sarela deferred to the gastroenterologists on the issue of the distance that should have been left between the external bumper and the skin. However, he took the view that, if it is accepted that there should have been play of 1-1.5 cm, and that the external flange was set at 2.5 cm on an abdominal wall also of 2.5 cm, then it would indicate there was too much tension.
- 75. In re-examination Mr Sarela was asked whether he could think of a plausible medical cause as to why the necrotic event occurred if it was found there was no tension. Mr Sarela told the court he could not conceive of another cause for necrosis other than excessive tension.
- 76. Mr Wyman concluded in the joint statement that, even if the skin-to-gastric lumen distance was 2.5 cm, then that would not usually be associated with excessive tension. He stated that in the vast majority of patients a snug but not overtight PEG fitting is acceptable, and not associated with any complication. He noted that there is a range of opinion as to how much slack is recommended. He referred to a paper by Best which recommended slack of just a few millimetres.
- 77. In cross-examination, Mr Wyman maintained his opinion that, even if flange- togastric lumen and skin-to-gastric lumen distances were the same, such that the external flange was flush to the skin, it would still be possible to pick the flange up and see a gap underneath because the tissues are pliant. There would therefore still be a little bit of play. He stated that some endoscopists fit the flange flush, close to or even on the skin's surface and that is accepted practice. It does not, he said, necessarily translate to undue tension. Mr Wyman agreed that if a device was fitted with undue tension, that would be substandard.
- 78. Mr Wyman relied on the Best article which summarised literature on the placement of PEG tubes and the recommended distance between the bumper and skin. He explained that he had referred to the paper to illustrate the wide range of practice as to the placement of a PEG. Best advocated positioning the external bumper approximately 2-3 mm away from the skin surface. Mr Wyman agreed that the positioning was a question of 'feel' that comes with experience.

HHJ Emma Kelly

[2024] EWHC 3156 (KB)
 79. Mr Wyman was taken to paragraphs 4.1 to 4.3 of his report where he discussed potential causes of the claimant's necrosis. He agreed that he had ruled out

excessive tension on the assumption that Dr Andrew's evidence would be accepted. However, he stated that excessive tension could be ruled out even if the flange had been fitted flush with the skin. He conceded that three of the four possible contributing factors he had identified in paragraph 4.3 of his original report, including poor wound healing and pressure on the external part of the PEG, were causes he had since ruled out following his discussions with Mr Sarela. The fourth factor he identified in his report, namely impaired gastric tissue perfusion arising from the stomach being distended by enteral feed or the weight of the feed pulling down the stomach on the internal bumper, was not mentioned in the joint statement. [This fourth factor was not pleaded in the Defence or Amended Defence, which likely explains why it was not the subject of joint discussion.]

- 80. It was put to Mr Wyman that, if the court accepted there was excessive tension, the likely cause of necrosis was that tension. Mr Wyman agreed with that proposition but explained that tension could come from different sources rather than necessarily being tension between the internal and external flanges. He explained that there is radial tension on the stomach wall from the rigid PEG tube itself. He further postulated that leakage around the side of the tube as it goes into the stomach could cause chemical irritation from gastric content or feed resulting in necrosis of the stomach wall. He also suggested that slack in the tube could cause the stomach to slip away from the abdominal wall allowing a leakage around the tube causing necrosis, otherwise known as periostomal leakage. Mr Wyman conceded he had not postulated periostomal leakage as a cause in his original report or discussed it with Mr Sarela. He however maintained that leakage can cause necrosis, which in turn causes further leakage. He noted that there was periostomal leakage in the claimant's case as she had four-quadrant peritonitis and a lot of feed in her abdomen. He considered that the surgeon's note from the emergency operation on 24 March 2016 suggested to him that the claimant's necrosis must have been quite small because the tube was still in the stomach.
- 81. In answer to questions of clarification I asked, Mr Wyman told the court possible causes of the necrosis included pressure around the tube itself, excessive tension, or feed escaping because there was too much slack but that he could not say which cause was most likely.

The gastroenterologist experts

- 82. Prof Gilmore and Dr Bird produced two joint statements, dated 22 May 2024 and 5 August 2024. The effect of those reports is that they agree on many issues:
 - The standard of reasonable care requires a PEG to be fitted without any tension between the internal and external bumpers and with a centimetre or so of 'play' between the two.
 - ii) If the skin-to-gastric lumen distance was found to be 2.5 cm, then the outer

[2024] EWHC 3156 (KB) bumper would have been right up against the skin surface.

- iii) If the skin to gastric lumen distance is found to be 1 cm, and the outer bumper was at 2.5 cm, then there would have been a reasonable amount of 'play'.
- iv) Any tension between the internal and external pump should be identified and corrected.
- v) If the court accepts the account given in Dr Andrew's witness statement, the procedure was performed to an acceptable standard save for the inaccuracy in documenting the measurements. Creating a record of a skin-to-gastric lumen distance that is incorrect by a factor of 2.5 does fall below a standard of reasonable care but, if the court accepted the evidence of Dr Andrew on the actual distance between the buffers, the error would not have resulted in any harm.
- vi) It is not standard practice to note in a patient's medical records the measurement at which the outer bumper is placed, the skin-gastric lumen distance, or the margin of 'play'. There is no standard way in which a report should be written or what measurements should be included in it. Endoscopy reporting computer software differs between hospitals and some versions will require a measurement to be documented whilst others will not. Whether a measurement is recorded or not is at the discretion of the endoscopist.
- vii) Failing to note a skin-to-gastric lumen distance in a patient's records does not fall below the standard of reasonable care.

Likely skin-to-gastric lumen distance and the standard of care

- 83. Prof Gilmore and Dr Bird were asked to comment on the likelihood of the claimant's skin-to-gastric lumen distance being 1 cm or 2.5 cm. Both experts acknowledged that neither of them was an expert on abdominal wall anatomy and its normal variations. Prof Gilmore noted that the claimant had a normal BMI and, taking into account relevant literature, a distance of 2.5 cm was the more likely. Dr Bird noted that the BMI was at the lower limit of normal and, also having reviewed the literature, took the view that 1 cm was more likely.
- 84. Prof Gilmore addressed the likely skin-to-gastric lumen distance in his written report. He opined in line 179: "*1 cm is at the lower limit of what might be expected in a very thin individual...[the claimant] appears slim but of normal build... The rectus abdominis muscle would be expected to be in the region of 9 mm and the subcutaneous fat, the other main component, can vary greatly.*" He referred to the Kim et al. study also relied on by Mr Sarela.
- 85. In cross-examination, Prof Gilmore agreed that 1.3 mm was a fair starting point for the claimant's likely gastric wall thickness although noted it could be more or less. He took the view that the confidence interval of the Chaves paper was necessarily

HHJ Emma Kelly [2024] EWHC 3156 (KB)

going to be less than for the Kim paper given the smaller number of patients in the Chaves study. He agreed that the conclusion to be drawn from the Chaves paper was that, in a group of 10 patients of the claimant's weight range, one had an abdominal wall thickness of 1 cm.

- 86. Concerning the Kim paper, he agreed that the claimant's PEG was likely located between the umbilicus and xiphoid levels. He noted that the angle of a PEG tract is not necessarily perpendicular to the skin surface. He recognised the authors of the Kim paper had only measured the fat at the umbilicus level. Prof Gilmore deferred to Mr Sarela's expertise as a surgeon regarding variations in abdominal fat thickness. His own experience was that he was not aware of any noticeable difference in the depth of the fat layer as one goes down the abdomen toward the umbilicus. [The Kim study found a mean fat thickness of 23 mm with a range from 4 to 54 mm.] Prof Gilmore agreed that the less fat an individual was, the lower the likely fat measurement. He acknowledged that it was significant that the Kim paper had used the thickest part of the muscle at each of the xiphoid and umbilicus and accepted that he had not highlighted this in his report.
- 87. Prof Gilmore explained he placed less weight on the length of the mature PEG tract as an indicator of the position in 2016 because a tract may contract or get longer as it matures. He nonetheless took the view that some evidential weight can be attached to the current tract length of 2.5 cm because he would be surprised if an original tract of 1 cm matured by as much as 250%.
- 88. Prof Gilmore agreed there would be some difference between the skin-to-gastric lumen distance depending on whether the stomach was inflated or deflated but he thought the difference would be fairly small. He agreed that the lumen of the stomach would drop down by a little bit when no longer under inflation.
- 89. Prof Gilmore was criticised for not addressing the range of the appropriate standard of care in his report. He explained that the only standard in practice is that there should be 'play' on the PEG tube; such that it can be moved backwards and forwards. He acknowledged that there was evidence suggesting the appropriate amount of 'play' ranged from a few millimetres to 1.5 to 2 cm and that some papers suggested there should be enough space to put a little finger under the flange. He explained that the important consideration was that the tube was able to move backward and forward when manipulated. The measured distance of the play was not the important issue. He agreed that if Dr Andrew had checked that there was sufficient 'play' in and out and rotated the tube, then he had fulfilled his duty. He did not agree that leaving only 2 or 3 mm would be regarded as acceptable by a reasonable, even if minority, body of gastroenterologists unless the doctor also satisfied themselves by appropriate feel.
- 90. Dr Bird concluded in his written report that in a thin person such as the claimant with a BMI of about 20, he would expect the skin-to-gastric lumen distance to be approximately 1 - 1.5 cm. He noted that the photograph of the trocar in the stomach shows the majority of the shaft in the stomach, suggesting there was minimal distance between the outer skin and the lumen of the stomach. In cross- examination, he agreed that the literature discussed with other experts looked at an abdominal wall depth in

circumstances where the stomach was not inflated.

91. In the joint statement, Dr Bird took the view that, even if the court found that the skin-to-gastric lumen distance and position of the external flange were both
2.5 cm, such positioning would not necessarily indicate substandard practice given the range of opinion as to how much 'play' is recommended.

- 92. In cross-examination, Dr Bird agreed that if the flange was set at 2.5 cm and the skinto-gastric lumen distance was also 2.5 cm there would be minimal 'play'. He did not however accept that it follows that there would be a risk of tension. He explained that if a flange is lying on the surface of the skin, that in itself does not cause tension. It would only be an issue if the tube was putting pressure on the skin. He agreed it was important to check to ensure that no tension existed and, if there was tension, it would be a breach of duty. He agreed that if the measurements in the operation note were accurate on their face, then the approach adopted by Dr Andrew would not be in keeping with the BSG guidance and other papers.
- 93. In re-examination, Dr Bird explained that there is a range of opinion as to the recommended 1 cm of 'play' as stated in the BSG guidelines including, for example, the manufacturer training material which states *"Tighten the tube until a slight resistance is felt without exerting excessive pull".* He agreed with Prof Gilmore's evidence that the appropriate standard was one of the feel, as opposed to a measurement of millimetres or centimetres. He opined that the minimum distance from the outer flange to the skin in keeping with the minimum standard required standard would be 2 mm.

Cause of necrosis

- 94. The gastroenterologists were not expressly tasked with addressing causation but certain aspects of their evidence touched upon the topic. In the joint statement, Prof Gilmore opined that, if the court found the skin-to-gastric lumen distance was 2.5 cm and the external flange positioned at 2.5 cm, that would leave insufficient play causing a risk of pressure necrosis in the wall of the stomach.
- 95. Prof Gilmore stated (in lines 126-130 of his report) that complications of PEG insertion are quite common and have been reported to occur in between 16-70%. Most complications are minor but major complications occur in about 3-5% of patients although peritonitis is very rare. He noted (in lines 185-188) that if the court accepts the defendant's case that there was 1.5 cm of play, then there was no danger of generating tension on the stomach wall. If the court however concluded that the outer bumper directly abutted against the skin, it *"might, if under tension, predispose to necrosis"*.
- 96. In cross-examination, Prof Gilmore accepted that when he 'consents' patients for a PEG procedure, the risks identified include necrosis. When asked about the risks of necrosis from excessive pressure between the bumpers, he stated *"I can conceive of no other credible mechanism"*. He did not accept that two days would be a short time for ischaemia to develop but agreed that it was fair to say that there would have to be quite a severe degree of compression for that to occur.
- 97. Prof Gilmore was asked about other potential causes of tension. He considered the risk of injury in pulling the PEG tube through the smaller hole made by the trocar

HHJ Emma Kelly

[2024] EWHC 3156 (KB) could theoretically be a cause of necrosis but he had not seen it in over 1000 cases.

He took the view that if it was a credible cause of necrosis, such an outcome would have been seen.

- 98. He was asked whether the weight of the feed inside the stomach could pull on the PEG, exerting pressure on the internal wound at the edge of the PEG, to cause necrosis. Prof Gilmore told the court he was not aware of such a theory being put to any tests. It was put to Prof Gilmore that such a cause was rare and unusual but had the potential to cause necrosis. Prof Gilmore said he was unaware whether it could cause necrosis but accepted it was a potential mechanism.
- 99. Prof Gilmore was asked about the risk that feed and gastric contents could come into contact with the area around the wound at the stomach lining and cause ischaemia. He stated there was a potential to cause auto-digestion but wasn't sure he would refer to it as ischaemia. He did not believe the feed in itself would cause damage. He noted that any stomach acid would be diluted by feed and did not consider it a likely cause of rapid necrosis. He opined *"I mean in medicine we're taught to never say never, but I find that hypothesis unlikely to be true"*. Prof Gilmore agreed with the conclusion of the authors of the Rahnemai-Azar et al. paper that there were several potential causes of a leak around the stoma. He also agreed with the authors of the Westaby paper that the failure of the wound to seal around the tube could cause leakage and agreed that was a theoretical possibility although he had not heard of it happening.
- 100. It was put to Prof Gilmore that there were several potential causes of the necrosis and he could not reliably say which one of those causes was the effective cause. He accepted he could not but stated there was one cause that was reproducible, that being the application of a bumper with severe tension from which the patient would get peritonitis. If however a tube was inserted 'as we normally do' this wouldn't happen. Prof Gilmore was asked if a fair way of putting it was to say if the bumper was set too tight, it increased the risk of the complication happening. He responded: *"Yes, I think one could almost guarantee it if one went about really exerting maximum pull on the tube".*
- 101. Dr Bird agreed in cross-examination that the manufacturer's warning 'special care should be taken to avoid necrosis' meant do not fit the device with too much tension. He agreed that Dr Andrew's evidence that there was 1–1.5 cm of excess tube did not mean the excess was so large to risk leakage. He agreed that on the claimant's factual case as to the skin-to-gastric lumen distance, the possibility of leakage was close to fanciful. It was put to Dr Bird that if the court concluded there was undue tension, the only realistic cause of the necrosis would be that tension. Dr Bird stated: *"It would be the leading cause. Yes."*
- 102. In re-examination, Dr Bird was again asked about the risk of leakage. He rather changed his position telling the court that there was a risk of leakage however the tube was set. He said this could arise when the gastric wall and abdominal wall had not formed a proper sandwich.

The neuro-rehabilitation/neurology experts

- [2024] EWHC 3156 (KB) 103. In their joint report, Dr Bavikatte and Dr Bowler agreed on the following:
 - i) The claimant had congenital cerebral palsy, epilepsy, autism, and learning difficulties, which preceded the placement of the PEG in 2016.

- ii) As a result of the episode following the PEG insertion:
 - i) The claimant sustained peritonitis and sepsis.
 - ii) There was an episode of hypoxia, which resulted in brain damage.
 - iii) There was a worsening of the claimant's neurological condition.
 - iv) There was a significant increase in the claimant's physical, cognitive, and psychosocial restrictions.
 - v) There was a significant change in the claimant's functionality and consequent dependence and needs.
- iii) The claimant's life expectancy after the PEG procedure is 47.19 years.
- 104. There is a dispute between the experts as to whether the claimant's pre-existing conditions were static/non-progressive neurological conditions or whether the claimant was deteriorating in any event. In the joint statement, Dr Bavikatte maintained that based on the history he had been given and the claimant's lay witness statements, the claimant's deficits before placement of the PEG were static. Dr Bowler disagreed and took the view, in light of medical records showing prior progressive deterioration, particularly in mobility and swallowing, that the complications arising from the index procedure caused an advancement of the pre-existing deterioration by a period of six years.
- Both experts were cross-examined. Dr Bavikatte accepted that when he prepared his 105. report, he was aware of the need to address the defendant's case on causation being limited to a six-year acceleration. He conceded that he had not referred to specific medical records in his report to support his conclusions. He explained he had based his opinion on the claimant's witness evidence, including history given by her parents, and the medical records. He conceded that there was contradictory evidence in some of the medical records but maintained he had discharged his duty to the court when preparing his report. It was pointed out to Dr Bavikatte that his abstract from the medical records did not reference a single medical record that pointed to deterioration. He apologised for not having put that detail in his report but maintained he had nonetheless considered all the facts and figures before reaching his opinion. He accepted that his lack of reference to the medical records in his report meant that neither the defendant nor the court would know what his opinion was as to the effect of relevant entries in the records. He further agreed that, if the court accepted there was a pre-existing deterioration in function, the court had no evidence from him as to the consequences of that on causation.
- 106. In cross-examination, Dr Bowler stated that the insult to the brain that occurs as part of cerebral palsy is a single one-off event but what happens thereafter becomes much

HHJ Emma Kelly [2024] EWHC 3156 (KB)

more complex. Musculoskeletal changes can progress and new problems, such as epilepsy, can develop. One has to make allowance for the effects of age superimposed upon the deficit that was present from birth.

- 107. He agreed that anticipating the future is generally very difficult. Dr Bowler agreed that an adult in their mid-20s, who was ambulant indoors, perhaps with a bit of assistance via hand-holding around the home, and who could walk to the carer's car, but was wheelchair dependent over a longer distance, would likely retain that sort of mobility to their mid-to-late 50s but would require hoisting by age 60.
- 108. Dr Bowler was asked about his approach to assessing advancement. He explained that estimating advancement is necessarily very approximate with very wide margins of error. He stated that he undertook an initial interpretation of the claimant's mobility, as that was the aspect of functioning most clearly described in the medical records, and then asked himself whether there was any reason to suppose that advancement in respect of other areas of functioning would be any different.
- Dr Bowler agreed that he had formed the view that, by 2016, the claimant's overall 109. level of mobility was very low and he deemed her immobile in the sense of being able to ambulate and transfer independently. He was taken to a series of medical records and acknowledged there was some fluctuation in the claimant's level of walking ability. He observed that close carers may accustom themselves to gradual decline such that it is not noticed by them. Whilst accepting the records showed some fluctuation in mobility, he stated that if one looks at the broad generality of the mobility from the time when the claimant was very young to the date of the PEG procedure, it showed a downward trajectory. He stated that there will have been periods when the function was above the general line, and times when it was below the line, but one has to look at the general evolution. Dr Bowler accepted he had not addressed the question of fluctuation in his report. He did not accept that he had envisaged the claimant being 'bedbound', as described in the medical record from 24 March 2016. He pointed to the position described in an ENT assessment in January 2015 as being the likely level of functioning immediately before the PEG procedure. He agreed that if the carer's evidence was accepted to the effect that the claimant was still mobilising in the home, was still going out and about and only using the wheelchair for longer distances outside, then there was no need to consider acceleration.
- I IO. In re-examination, Dr Bowler was taken through various medical records between 2003 and 2016. He interpreted the records as showing the claimant as progressing from having reasonably good mobility with little need for support, to needing a wheelchair occasionally when outdoors, to having little or no independent mobility indoors, even with assistance, and requiring a wheelchair. He said it was less clear but possible that she needed assistance with transfers.
- Dr Bowler was asked about incontinence. His view was that for clinicians to describe someone as incontinent of urine, he would expect it to be more than just an occasional occurrence of incontinence. He did however recognise that a GP may describe an individual as being incontinent if they required ad hoc management of

[2024] EWHC 3156 (KB) their bladder function with pads. He agreed that the peritonitis did not change the pre-existing bowel irrigation requirements.

- Dr Bowler agreed that few patients with cerebral palsy, who were previously mobile, would end up with a tracheostomy. He agreed that the main factor leading to his conclusion that the claimant would have required a tracheostomy, in any event, was the risk of aspiration. He took the view that her decline in swallow function and mobility also played some role. He agreed that video fluoroscopy provides the gold standard analysis of what can be seen at the time of examination. He however noted that, regardless of what a video fluoroscopy shows, if a patient is eating less well and losing weight, then swallowing has deteriorated. He did not accept the claimant's swallow was normal before the PEG procedure, noting she was already requiring mashed, softened foods and thickened drinks. He agreed the video fluoroscopy showed no sign of aspiration at the date of the examination on 18 November 2015 but noted that only limited foods were tested. He maintained his opinion that the claimant would have required a tracheostomy, in any event, in six years.
- I I 3. In re-examination, Dr Bowler highlighted that the records after the peritonitis show that the claimant suffered an increasing number of repeat chest infections and pneumonia. He explained this was significant as one would expect any deficit to have been maximal in the months after the PEG procedure but then to have improved to some extent. His interpretation of the increasing frequency was that it evidenced a continuation of the pre-existing deterioration rather than being a consequence of the peritonitis.

Life expectancy

- 114. The joint report reveals a dispute between the experts as to the claimant's life expectancy but for peritonitis and sepsis. Dr Bavikatte concludes that her life expectancy would have been 78.52 years, in light of his earlier conclusion that the claimant's pre-existing condition was static. Dr Bowler concludes that the life expectancy would have been 62.7 years, given that the claimant's condition was already deteriorating. He accepted that if the court were to find that the claimant could walk unaided, and that her condition before the placement of the PEG was static, then Dr Bavikatte's assessment of life expectancy was accurate.
- I I 5. In cross-examination, Dr Bavikatte was asked why he had not proffered an opinion on life expectancy based on the defendant's factual case that the claimant was already deteriorating. He did not always answer the questions put to him but eventually accepted that he had not dealt with that aspect of life expectancy.

The applicable law

The standard of care

The correct approach to assessing the standard of care is not in dispute. In *Bolam v Friern Hospital Management Committee* [1957] I WLR 582 at 586-587 the applicable standard of care is described in the following well-known terms:

[2024] EWHC 3156 (KB) "...The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well established law that it is sufficient if he

exercises the ordinary skill or an ordinary competent man exercising that particular art...

... [A doctor] is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in this particular art ... Putting it the other way around, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion that would take a contrary view."

^{117.} That is not to say that the court will not scrutinise the medical practice said by a doctor to be a proper one. The House of Lords in *Bolitho v City and Hackney Health Authority* [1998] AC 232 at p243A-D:

"... in cases of diagnosis and treatment there are cases where, despite a body of professional opinion sanctioning the defendant's conduct, the defendant can properly be held liable for negligence ... In my judgment that is because, in some cases, it cannot be demonstrated to the judge's satisfaction that the body of opinion relied upon is reasonable or responsible. In the vast majority of cases the fact that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion. In particular, where there are questions of assessment of the relative risks and benefits of adopting a particular medical practice, a reasonable view necessarily presupposes that the relative risks and benefits have been weighed by the experts in forming their opinions. But if, in a rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible."

Assessing witness reliability

- 118. The lay witnesses in this case were giving evidence about index events that took place in March 2016, around 8½ years before the trial. In the case of the claimant's lay witnesses, they were also trying to recall details of the claimant's progression of her level of functioning over many years before the PEG procedure. The effect of the passage of time on memory is a factor that calls for consideration.
- The fallibility of human memory and approach to assessing witness reliability was considered by Leggatt J in *Gestmin SGPS SA v Credit Suisse (UK) Limited* [2013] EWHC 3560 (Comm) in the following terms:

"22. ...the best approach for a judge to adopt in the trial of a commercial case is, in my view, to place little if any reliance at all on witnesses' recollections of what was said in meetings and conversations, and to base factual findings on inferences drawn from the documentary evidence and

120. The approach in *Gestmin* is equally applicable to fact-finding exercises in other contexts. In *Carmarthenshire County Council v Y*[2017] EWFC 36, Mostyn J endorsed the approach in *Gestmin*:

"In my opinion this approach applies equally to all fact-finding exercises, especially where the facts in issue are in the distant past. This approach does not dilute the importance that the law places on cross- examination as a vital component of due process, but it does place it in its correct context."

Contemporaneous medical records

- 121. In this case, the accuracy of certain medical records has been called into question by various witnesses. A number of the claimant's lay witnesses contended that some of the medical records over the years before 2016 are not an accurate record of the claimant's level of functioning. Dr Andrew contended that his endoscopy report contained an inaccurate record of the skin-to-gastric lumen distance.
- The approach to assessing the weight to be attached to contemporaneous medical records was considered in *Synclair v East Lancashire Hospitals NHS Trust* [2015]
 EWCA Civ 1283 where Tomlinson LJ at [12] held:

"...it is too obvious to need stating that simply because a document is apparently contemporary does not absolve the court of deciding whether it is a reliable record and what weight can be given to it. Some documents are by their nature likely to be reliable, and medical records ordinarily fall into that category..."

Tomlinson LJ continued at [12] by endorsing the approach of HHJ Collender QC, sitting as a judge of the High Court, in *EW v Johnson* [2015] EWHC 276 (QB) at [71]:

"...As a contemporaneous record that Dr Johnson was duty bound to make, that record is obviously worthy of careful consideration. However, that record must be judged alongside the other evidence in the action. The circumstances in which it was created do not of themselves prevent it being established by other evidence that that record is in fact inaccurate."

- 124. Tomlinson LJ accepted at [15] the general proposition concerning the inherent reliability of clinical notes in many cases.
- In Manzi v King's College Hospital NHS Trust [2018] EWCA Civ 1882, Sir Ernest Ryder at [18-19] accepted that the propositions discussed in Synclair were not in dispute:

"Clinical records are made pursuant to a clear professional duty, serious failure in which could put at risk a practitioner's registration. Moreover,

they are not compiled simply as a historical record, they fulfill an essential and ongoing purpose in informing the care and treatment of a patient. Contemporaneous records are for these reasons alone inherently likely to be accurate."

126. Subsequent clinical negligence claims, such as Cotter J in HTR v Nottingham University Hospitals NHS Trust [2021] EWHC 3228 (QB) and myself in Richins v Birmingham Women's and Children's NHS Foundation Trust [2022] EWHC 847 (QB) have adopted the aforementioned approach to assessing witness reliability and the weight to be attached to medical records.

Causation

127. The House of Lords in *Gregg v Scott* [2005] 2 AC 176 concluded by a majority that the burden of proof rests on a claimant bringing a medical negligence claim to prove, on the balance of probabilities, that the negligence caused the injury. Lord Phillips at [174] sets out the correct approach:

"...subject to the exception in *Fairchild's* case, a claimant will only succeed if, on balance of probability the negligence is the cause of the injury. If there is a possibility, but not a probability, that the negligence caused the injury, the claimant will recover nothing in respect of the breach of duty..."

128. Where there are competing alternative causes, a claimant can prove causation by relying on epidemiological evidence to prove that the breach of duty doubled the risk of causing the injury when compared to all the other potential causes. In *Sienkiewicz v Greif (UK) Ltd*[2011] UKSC 10 at [93] Lord Phillips held:

"Where there are competing alternative, rather than cumulative potential causes of a disease or injury, such as in *Hotson v East Berkshire Area Health Authority* [1987] AC 750, I can see no reason in principle why epidemiological evidence should not be used to show that one of the causes was more than twice as likely as all the others put together to have caused disease or injury."

129. In O'Connor v The Pennine Acute Hospitals NHS Trust [2015] EWCA Civ 1244, the claimant suffered an injury to her femoral nerve. The Court of Appeal considered the approach to be taken where several possible causes are suggested. Jackson LJ at [64] explained this in the following way:

> "It is not an uncommon feature of litigation that several possible causes are suggested for the mishap which the court is investigating. If the court is able, for good reason, to dismiss causes A, B and C, it may be able to reach the conclusion that D was the effective cause. But the mere elimination of A, B and C is not of itself sufficient. The court must also stand back and, looking at all the evidence, consider whether on the balance of probabilities D is proved to be the cause."

HHJ Emma Kelly [2024] EWHC 3156 (KB)

1 30. On the facts of O'Connor the defendant argued for an alternative explanation for the injury to the femoral nerve. The trial judge rejected defendant's explanation and found the injury to have been caused by negligent surgical trauma, treating the absence of other plausible explanations as supporting his

conclusion, not as providing the sole basis for it. The Court of Appeal upheld such an approach concluding at [84]:

"The fact that the defendant had not proffered any plausible explanation for the claimant's injury consistent with the exercise of due care did not convert the case into one of res ipsa loquitur. Nor did it reverse the burden of proof. Nevertheless this was a material factor, which the judge was entitled to take into account."

Findings of Fact

The claimant's skin to gastric lumen distance on 22 March 2016

- 131. The contemporaneous medical record in this case, namely the endoscopy report, records the skin-to-gastric lumen distance as 2.5 cm. Against the context that such records are inherently likely to be accurate (per *Synclair* and *Manzi),* that is very important evidence.
- 132. What is however apparent is that any assessment of the actual skin-to-gastric lumen distance will only be an approximation. No witness (Dr Andrew nor the experts) suggested that there would be any clinical reason to measure the skin- to-gastric lumen distance when performing this procedure and Dr Andrew accepted he did not do so on this occasion.
- Dr Andrew is the only witness who has direct knowledge as to the presenting clinical 133. position on 22 March 2016. (Nurse McCann was also present during the procedure but does not comment on this issue.) In his two witness statements, the second prepared to clarify evidence given in the first, Dr Andrew asserted that the skin-togastric lumen distance was 1 cm. A curious feature of Dr Andrew's oral evidence was his revelation in re-examination that, once the stomach was no longer under the inflation of the endoscope, the claimant's skin- to-gastric lumen distance would have been roughly 2.5 cm. This answer was given in response to an open question. He repeated this position in answer to a question of clarification I asked. It is staggering that Dr Andrew did not consider it relevant to include this evidence in his written witness statement. It is a significant concession. It means that, at the conclusion of the procedure, the external bumper, if fixed at 2.5cm as recorded in the endoscopy report, must have been lying snug to the claimant's skin. This is at odds with para. 15 of Dr Andrew's first statement where he stated that there would have been about 1.5 cm between the external bumper and the skin surface. It also means that the recording of the skin-to-gastric lumen distance in the endoscopy report at 2.5 cm was correct on its face, contrary to Dr Andrew's written and oral evidence that there was an error caused by the reporting software.
- 134. I make it clear that I consider Dr Andrew was doing his best to assist the court with his written and oral evidence and do not for one moment take the view he was

HHJ Emma Kelly [2024] EWHC 3156 (KB)

deliberately trying to mislead. The reality of the position is however that he has been asked to recollect the minutiae of what was a routine and quick procedure (one Dr Andrews accepted took around 13 minutes from start to return to the recovery room) that took place over 8 years ago. The fact that the skin-to-gastric lumen distance was not even a measurement that was needed for

clinical reasons exacerbates the difficulties of him now commenting on the fine detail of this topic. In addition to Dr Andrew's revised position in re- examination, other aspects of his evidence cast doubt on the reliability of his recollection that the skinto-gastric lumen distance under inflation was 1 cm.

- i) Dr Andrew's evidence was that the reporting software preset the skin- togastric lumen distance to 4 cm so the operator writing the report had to change the distance. If so, it does not make sense why Dr Andrew changed the 4 cm to 2.5 cm if he thought the correct measurement was 1 cm. He made a conscious decision to change the figure from the default 4 cm so his approach is not explicable by him simply ignoring the question. It is however consistent with his belief at the time that the correct figure was 2.5 cm. His explanation that he changed it to 2.5 cm because that was the distance at which he set the flange is illogical as he knew the software descriptor was not of the flange to gastric lumen distance.
- ii) Dr Andrew admitted his clinical record was not accurate. A failure to make an accurate clinical record is a breach of the General Medical Council's Good Medical Practice publication. Dr Andrew explained that there was a free text box under the heading 'Aftercare and Treatment'. If he thought at the time his clinical record was inaccurate, he could have used the free text box to clarify the position as to the inaccurate recording of the skin-to-gastric lumen distance. The fact that he thought it appropriate to leave a clinical record in an inaccurate state is a cause for concern.
- iii) There were times during cross-examination when Dr Andrew did not directly answer a question asked of him. When asked whether he accepted that his clinical record was inaccurate on its face, the question had to be asked three times before a clear answer was given.
- iv) At other times, parts of his evidence were internally inconsistent. At one point in cross-examination, Dr Andrew suggested that he would not have known that the reporting software would record the skin-to-gastric lumen distance as 2.5 cm until the report had been printed, by which time the computer system was locked such that he could not go back and edit the record. That was at odds with earlier evidence he gave to the effect that he could use the free text box as a workaround to correct the error.
- v) Dr Andrew's first witness statement asserted that, after the procedure, he had spoken to the claimant's father and offered an overnight stay as a precaution but the father was very keen to take the claimant home. In cross-examination he was taken to the medical notes which recorded *"Dr Andrew reviewed patient. It is alright to go home when ready."* Dr Andrew accepted that there was no record in the notes as to an overnight stay being offered or to the claimant's father wanting to take her home. He told the court he had a clear

recollection of speaking about an overnight stay but conceded that perhaps he had those discussions directly with the hospital staff only. The fallibility of accurate memory so many years after the event is demonstrated by this exchange.

- 135. For the aforementioned reasons, I have concerns as to the reliability of Dr Andrew's recollection that the inflated skin-to-gastric lumen distance was 1 cm. Other aspects of the case add to the doubts as to the reliability of Dr Andrew's recollection.
 - Dr Andrew accepted that he had been interviewed for an internal investigation in 2016 leading to a report, dated 30 June 2016, by Consultant Surgeon Martin Richardson. That report makes no mention of either the endoscopy report being inaccurate as regards the skin-to- gastric lumen distance or that the inflated distance was only 1 cm.
 - ii) The claimant's solicitor sent a letter of claim to the Defendant on 5 July 2018. The defendant responded by letter dated 9 May 2019. The response did not assert that the skin-to-gastric lumen distance was recorded incorrectly in the endoscopy report, that the correct distance was 1 cm, or that around 1.5 cm of play had been left in the tube. The first time the defendant asserted that the skin-to-gastric lumen distance was only 1 cm, and thus there was around 1.5 cm of play, was in the Defence, dated 27 April 2023. It is highly surprising that it took the defendant so many years to proffer this factual case.
- 1 36. The gastroenterology and general surgeon experts were impressive witnesses. The gastroenterologists acknowledged that neither of them possessed the same level of expertise as the general surgeons as regards abdominal wall anatomy and its normal variations. As such, the evidence from general surgeons holds greater weight although I accept that the experienced gastroenterologists are also placed to inform this issue. Each expert was cognisant, to varying degrees, of the limitations in using scientific literature or the current length of the claimant's PEG tube length as bases for determining the claimant's skin-to- gastric lumen distance on 22 March 2016. In my judgment, the balance of the expert evidence does however point to the probability that the claimant's skin- to-gastric lumen distance was around 2.5 cm rather than around 1 cm for the reasons discussed below.
- 137. When the experts were preparing their reports, they would not have been alive to the significant difference that Dr Andrew revealed in his oral evidence between his recollection as to the depth under inflation (1 cm) and depth at the end of the procedure (2.5 cm). The defendant's general surgeon expert, Mr Wyman, told the court he would expect any difference between the skin-to- gastric lumen distance between the position under and not under inflation to be minimal. Prof Gilmore agreed. That evidence suggests if Dr Andrew is correct as to the skin-to-gastric lumen distance between 2.5 cm at the end of the procedure, it was unlikely to have been as small as 1 cm under inflation.
- 138. None of the papers referred to by the experts suggest that the authors collected their data in circumstances where a patient's stomach was under inflation. The more appropriate comparison should therefore be between the claimant's stomach not artificially inflated (2.5 cm on Dr Andrew's oral evidence) and the data in the papers.

HHJ Emma Kelly

[2024] EWHC 3156 (KB) There are recognised limitations in conducting a comparison exercise but some useful analysis is possible. i) The Chaves paper involved a small study of 60 patients, of whom just 10 were in each of the underweight and normal weight categories. Prof Gilmore and Mr Sarela agreed when cross-examined that the data in the paper was consistent with 1 in 10 patients in the claimant's weight category having an abdominal thickness of 1 cm. The other 9 in 10 patients had a greater abdominal thickness. The paper indicates that the mean abdominal thickness of a patient with a BMI of 20 (as the claimant had) was in the region of 2 cm. To the abdominal depth, one must add the gastric wall thickness of approximately 1.3 mm (accepted under cross-examination by Prof Gilmore and Mr Sarela.) A skin-to-gastric lumen distance as low as 1.13cm would thus fall at the lowest end for patients of the claimant's weight category whereas the mean distance would be around 2.13 mm. The latter is self-evidently far closer to the

2.5 cm contended for by the claimant, and indeed Dr Andrews, once the stomach is no longer inflated.

- The Kim paper has limitations as it does not consider the abdominal muscle thickness at the same position as the claimant's PEG nor does it consider the subcutaneous fat thickness at anything other than the umbilicus level. However, standing back and looking at the data in the paper as a whole, it demonstrates that a skin-to-gastric lumen distance of as low as 1 cm would represent a patient at the very lowest end of the spectrum.
- 139. Dr Andrew's revised position that the claimant's skin-to-gastric lumen distance at the end of the procedure was 2.5 cm is thus entirely in keeping with the generality of the literature notwithstanding the limitations of the papers.
- In my judgment, one has to be very slow to draw any conclusions from the bumper-140. to-bumper length of the claimant's current PEG tube. Several factors make drawing a comparison risky: the claimant's current PEG is sited in a different abdominal position; the claimant has since gained weight; the fixing of the external bumper on a new tract can lead to the tract maturing to match that position; subsequent scarring and granulation can have an effect, and the personal preference of clinicians maintaining a mature tract can result in the outer bumper being set at different positions. Of the claimant's experts, Mr Sarela was more enthusiastic than Prof Gilmore as to the weight to be attached to the current tube length as an indicator of the likely skin-to-gastric lumen distance on 22 March 2016. Both experts told the court that each of the variables makes no more than a few millimetres of difference. Whilst some of the variables may make for only a few millimetres of difference, the personal preference of a clinician could have a significant impact. In light of the multiple variables, my conclusion is that little can be safely drawn from the tube length of the current PEG.
- 141. Whilst Dr Andrew has a clear recollection that the skin-to-gastric lumen distance

HHJ Emma Kelly [2024] EWHC 3156 (KB)

under inflation was around 1 cm, the guidance in *Gestmin* dictates that such evidence must be treated with caution. For the reasons discussed above, having considered the contemporaneous medical record, Dr Andrew's evidence as a whole (including his material clarification in re-examination), how the defendant's case on this topic has developed over time and the expert evidence, I find as a fact that, on the balance of probabilities, the claimant's uninflated skin-togastric lumen distance on 22 March 2016 was around 2.5 cm. The use of the word 'around' is deliberate. This is not a measurement that was or should have been taken at the time and thus can only be an approximation.

The claimant's level of functioning in the period prior to 22 March 2016

- 142. The extent of any dispute between the parties as to the claimant's level of functioning in the period before the procedure on 22 March 2016 narrowed as the trial proceeded. Mr Bradley conceded in the claimant's closing submissions that by March 2016, the claimant presented with a relatively high level of disability and her function was likely deteriorating. The claimant no longer sought to rely on Dr Bavikatte's evidence that the claimant's condition was static before the PEG procedure. This concession was sensible as Dr Bavikatte's evidence was demonstrably partisan. He had not considered the totality of the evidence, particularly the detail of the medical records, and proceeded only to consider the high point of the claimant's factual case. The claimant however contended that the evidence from the claimant's parents and carers as to the claimant being ambulant with assistance indoors and wheelchair-dependant outdoors is credible. The defendant contended that the claimant's functionality was already deteriorating between 2003 and 2016.
- 143. The claimant's parents and carers are the only witnesses with direct knowledge of the claimant's abilities over the years leading to the procedure in March 2016. Each of their witness statements was prepared in November 2023, some $7\frac{1}{2}$ years after the index event, and required an even longer memory as to the progression of the claimant's condition over the two decades since 2003. The cautionary advice in *Gestmin* is apposite to the assessment of this lay evidence. It is also relevant that none of these witnesses are independent and each has an obvious close bond with the claimant, factors which may impact upon the objectivity with which they can recollect events. That is not to say that the witnesses are deliberately misleading the court but it does risk unconscious bias affecting the accuracy of their answers.
- 144. The circumstances in which the witness statements of the claimant's parents and that of Mrs Sheasby were prepared are very unsatisfactory. The identical terms of a number of the paragraphs, indeed multiple paragraphs as between the parents, demonstrates that the evidence cannot be their own words. In my judgment, the most likely explanation is that these three witnesses discussed their evidence before giving what amounted to joint instructions to the claimant's solicitor, who then drafted a statement and cut and pasted paragraphs into other statements. This approach undermines the cogency of the evidence as it is impossible to determine the actual words of each witness.
- 145. The evidence of Mrs Sheasby painted a rosy picture of the claimant's level of functioning before the PEG procedure. Her detailed account of the claimant's

HHJ Emma Kelly [2024] EWHC 3156 (KB)

typical routine portrayed a young woman with a high degree of independence; able to get herself out of bed and to the toilet, to largely wash and dress herself, communicate her breakfast wishes, and assist carers with domestic tasks such as cleaning up dishes and vacuuming. Her lunchtime routine was said to extend to lunch dates or meet-ups with friends. Meals such as jacket potatoes, sandwiches, or soup were consumed. Trips out were usual, including short walks without a wheelchair. Neither of the claimant's parents sought to demur from the account given by Mrs Sheasby to any material extent.

- 146. What is startling is the extent to which Mrs Sheasby's and the parents' recollection of the progression of the claimant's functionality differs from that recorded in the medical records. The court has the benefit of compendious contemporaneous medical notes spanning many years. In addition to the cogency to be attached to medical records generally (per *Synclair*), it is of note that the records concerned were compiled by a wide variety of treating clinicians. It is far less likely that multiple medical professionals all made errors in their note-taking. That undermines the evidence of the claimant's parents and Mrs Sheasby to the effect that a number of the medical records give an inaccurate, that is to say overly negative, reflection of the claimant's level of functioning.
- 147. In paragraph 30 of his skeleton closing submissions, Mr Barnes provided a detailed analysis of entries in the medical records. The claimant's lay witnesses were taken to many of those entries in cross-examination. The couple of years before March 2016 is likely to provide the best insight into the claimant's probable level of functioning just before the PEG procedure. Before considering that period, it is worth noting a wheelchair referral form, dated 20 March 2012, completed by Jeanette Millward of the physiotherapy team. The form asked a variety of questions with multiple-choice answers given as follows:
 - Able to walk around the home with assistance only (but not requiring aids).
 - Ability to transfer with 1-2 people. The other answer options on the form were 'independent' and 'hoist'.
 - Using a wheelchair every day both indoors and outdoors. The form does not make it clear whether 'indoor' use means only the home or other indoor environments such as a café.
 - Time sitting in a wheelchair: 2-8 hours.
- 148. There are a series of useful entries for the period from October 2014:
 - i) 28 October 2014: GP entry noting "seen with mother and carer. Concerned re weight loss – 1 stone in 10/12, pale, hair thinning, sleeping +++, not able to walk as far, falling, incontinent of faeces incontinence of urine, not appear to be in pain, less sociable than used to be, will eat if given food but does try to avoid meals, constipated – long standing problem."
 - ii) 4 November 2014: GP's referral letter to Adult Rehabilitation Team: "...Of
 late she has started falling often and is unable to walk as far as she used to.

[2024] EWHC 3156 (KB) She is incontinent of faeces and urine and I am arranging some investigations for her recent weight loss."

- 4 December 2014: GP entry noting: Problem swallowing, for some time, does eventually get food down, has soft diet, not opening mouth as wide as used to, food visible in mouth, still losing weight..."
- iv) 14 December 2014: GP's referral letter to Queen's Hospital, Burton upon Trent: "...she has had problems with swallowing for quite some time and she struggle to get food down. She has a soft diet, but food is sometimes visible in her mouth for quite a long time. They feel she is not able to open her mouth as wide as she used to. She has been loosing [sic] weight over the last few months and has lost about a stone in weight over the last 10 months."
- v) 5 January 2015: Consultant ENT Surgeon's letter to GP: "has a long standing history of swallowing difficulties but apparently this has become more noticeable in the last year. She appears to hold her food in the mouth and seems reluctant to swallow. There are no actual choking episodes. She appears to manage liquids satisfactorily. There has been some observed weight loss of approximately 1 stone in the past year. I note she has quite severe cerebral palsy with learning difficulties and epilepsy. According to her carer, there has been decline in several functions over the past year or two. She was previously able to walk but can now only transfer from her wheelchair..."
- vi) 28 January 2015: GP entry noting: "chat with mother, worried, as started passing urine +++, mum thinks is not a urine infection as urine clear, flooding out of pad in the morning, which is out of keeping for her, sweating +++...Dementia screening declined not appropriate – patient not able to communicate, has severe learning difficulty."
- vii) 28 April 2015: Nursing Care plan: "[the claimant] does not communicate verbally but can use some signs to indicate her needs in context to her environment and with others who know her well...continence is an issue and finding the right products to help her manage her continence...[the claimant] is unable to communicate the needs of what she wants to do...
- viii) 18 November 2015: Videofluoroscopy report: "...[The claimant] has been coughing, retching and vomiting all diet and fluids. A PEG has been discussed but currently eats pre-mashed diet and naturally thickened fluids. [The claimant]is reported to be on PPI once a day for reflux. There are ongoing reports of reflux symptoms i.e. small amounts of stomach contents have been seen on her pillow at night...evidence of oropharyngeal dysphagia characterised by oral stage difficulties; reduced oral control; reduced chew and manipulation of bolus. Her pharyngeal stage was largely intact although normal consistencies of diet and fluids were not assessed due to baseline recommendations...on today's assessment there were no signs of aspiration or significant residue that would explain [the claimant's]symptoms. Her

symptoms suggest she may have hypersensitivity in her pharynx and larynx, possibility due to laryngopharyngeal reflux..."

- ix) 8 December 2015: GP entry noting: *"has recently had videofluoroscopy, advised ENT referral, being sick after some meals every few days."*
- x) I December 2015: GP's referral letter to Queen's Hospital: "has recently been struggling to eat orally, often coughing, retching and vomiting after all diet and fluids. She currently eats a pre-mashed diet with syrup thickened fluids and is treated for reflux with a PPI."
- xi) 20 January 2016: Enteral Feeding Dietitian's letter to GP: "in view of her increasing difficulties to meet her dietary and fluid requirements, mum would like to be referred to a gastroenterologist for consideration of placement of a PEG...I am aware of her recent videofluoroscopy results which suggest her swallow is essentially normal but suggested ENT review is required due to her reflux..."
- xii) 2 February 2016: Consultant ENT Surgeon's letter to GP: "no specific ENT treatment required. However, may benefit from PEG if this relieves her difficulty eating and maintains fluid intake..."
- xiii) 4 February 2016: GP entry noting: *"…having problems eating, looking towards peg feeds, being sick while eating, medication all coming up…"*
- xiv) 8 February 2016: GP's urgent gastroenterology referral letter to Good Hope Hospital: "there have been concerns over the past few weeks about her increasing difficulties with swallowing...she has recently started to have difficulty tolerating her medication..."
- xv) 18 February 2016: Nutrition nurse's letter to claimant copied to GP: "...you attended clinic today in your wheelchair, accompanied by your Mom, Dad and your Carer, you remained quite sleepy throughout the discussion. Your parents and carer report that your food tolerance varies from day to day, sometimes tolerating multiple spoons but other times becoming quite fatigued, particularly with fluids which can be difficult to take enough of. We also discussed that you suffer vomiting after eating food but again there appears to be no particular pattern for this and it can vary..."
- xvi) 22 March 2016: PEG Procedure admission form. Notes that the patient has had recent seizures, can transfer, needs assistance but not a hoist or pat slide.
- xvii) 24 March 2016: Critical care admission notes: "...Normally bedbound..."
- 149. Dr Bowler interpreted the medical records from 2003 as showing the claimant's level of mobility as being a general downward evolution, with some periods when the function was better or worse than the general trend. In my judgment, Dr Bowler's assessment of the records depicting a downward trajectory is a fair one. Not only concerning the question of mobility but also as to continence and ability to intake

fluids and foods orally. His opinion accords with parts of the evidence given by

Molly Evans and Lois Evans. Their evidence was more

compelling than that of the claimant's parents and Mrs Sheasby. Molly and Lois were much readier to make concessions as to the accuracy of the medical records. Molly Evans was particularly frank and, in my judgment, the most objective. It is however noteworthy that Molly Evans was adamant that the claimant retained the ability to mobilise short distances with light touch support by way of hand-holding. Lois Evans accepted what she referred to as the 'slowing down' of the claimant over the years leading up to the PEG procedure. It may be that their slightly more distant relationship to the claimant, and the fact that neither of them now cares for the claimant, made it easier for them to be more objective.

- 150. In my judgment, the claimant's functioning had deteriorated over the years leading up to the PEG procedure on 22 March 2016. Such a position is documented in the medical records, indeed conceded by the claimant in closing submissions. Contrary to aspects of the evidence given by the claimant's parents and Mrs Sheasby, there is no evidence to suggest that the accounts given in multiple different contemporaneous medical records are inaccurate. Mrs Sheasby's account as to the active, semiindependent lifestyle the claimant was living may have been correct several years before but, by March 2016, the claimant's abilities had reduced significantly. She had good days and bad days but, overall, she was deteriorating. Taking all the evidence into account, I find as a fact that, on the balance of probabilities, the claimant's level of functioning immediately before the PEG procedure was as follows:
 - i) The claimant was incapable of walking around her ground-floor cottage independently. She could, however, mobilise short distances in the cottage, such as from a sofa to a chair, or from her bed or chair to the toilet, but required a carer to stand next to her, provide encouragement and hold her hand. (Molly Evans accepted the need for assistance when cross-examined and Lois Evans accepted this was routinely the case.) Transfers required assistance from a carer by way of a helping hand and encouragement. The claimant could not be described as 'bedbound'.
 - ii) The wheelchair was usually kept in the carer's car and the claimant could walk from the cottage to the car on 'good days' with encouragement and handholding. However, her deterioration was such that on 'bad days' it is probable that the claimant needed to be transferred to the car by wheelchair.
 - iii) A wheelchair was required for trips outside the home.
 - iv) The claimant's ability to swallow both liquids and solids had deteriorated. Contrary to the evidence of some of the claimant's witnesses, the concerns on this topic were not limited to primarily fluid intake but extended to concerns about her ability to eat food. The days of eating jacket potatoes and sandwiches had long since passed. The claimant was struggling to maintain her weight notwithstanding her diet of mashed foods and thickened fluids.

Keeping medication down was also a concern. The very fact that a decision had been made to move to PEG tube feeding, supports the deterioration in this regard. The expectation was that the PEG would be used, initially at least, to supplement oral fluid and food intake.

- v) The claimant was largely incontinent of urine and faeces. The carers had moved to a rectal irrigation system in around 2013. Urinary continence had deteriorated although the claimant retained some daytime control with accidents from time to time.
- vi) The claimant's communication was limited to a small range of Makaton signs but that did enable her to communicate very basic needs.

The standard of care and breach of duty

- In their joint report, Prof Gilmore and Dr Bird agreed that the standard of reasonable 151. care required "the PEG to be fixed without excessive tension with a centimetre or so of 'play' between the two". That conclusion was reflected in paragraph 9(ii) of the pleaded particulars of breach of duty which alleged a failure to leave 'a centimetre or two of play between its position on the line and the surface of the skin'. However, after the gastroenterology oral expert evidence, Prof Gilmore and Dr Bird largely agreed the required standard of care was to ensure sufficient 'play' on the PEG tube rather than a focus on a specific measurement of required millimetres or centimetres of spare tubing. Prof Gilmore considered: "The actual distance is not crucial. What is crucial is that play; that the tube can be moved backwards and forwards and rotated to ensure that it is not jammed tight immovably against the ..internal [bumper] against the wall of the stomach ... "Dr Bird agreed that Prof Gilmore's description of the standard was a good way of putting it. He was more prepared to be drawn on actual measurements, considering the appropriate 'play' as being 'up to one *centimetre* 'but could be as low as two millimetres.
- 152. The standard of care to be applied is thus one whereby the PEG must be fitted to ensure there is 'play' with no undue tension. The extent of 'play' is not something to be measured in mm or cm but a question of feel.
- Paragraphs 9(i) [inserting the PEG with too much tension between the bumpers] and(iii) [failing to detect the tension and correcting it before concluding the procedure] of the Amended Particulars of Claim reflect the standard of care.
- 154. The claimant submitted that, on the balance of probabilities, there was undue tension on the basis that:
 - It is highly unlikely sufficient play could have been left if the skin-to- gastric lumen distance was 2.5 cm and the outer flange was also set at 2.5 cm.
 - Even if Dr Andrew had been attempting to adopt the method of allowing only a few millimetres of play, such an account is undermined by Dr Andrew's

own evidence that he left 1 - 1.5 cm of play.

Dr Andrews is an inherently unreliable witness in other respects (such as the iii) timings of the procedure and the endoscopy photographs, his

suggestion that the claimant's father wanted an early discharge, the 7- year time lapse before a positive case was averred and his admission that his clinical record was inaccurate) such that his evidence on leaving sufficient play should not be accepted.

- 155. The defendant submitted that the claimant cannot prove on the balance of probabilities there was a breach of duty through excessive tension on the basis that:
 - i) Insofar as the claimant seeks to rely on the injury to prove a breach, such an argument should be rejected as there are several potential causes of the injury, which may occur despite the exercise of reasonable care and skill. [I did not interpret the claimant's submissions as seeking to advance this argument and, in any event, agree that the mere existence of the injury is not an appropriate matter to take into account when determining any breach of duty in this case.]
 - ii) Neither the skin-to-gastric lumen nor bumper-to-gastric lumen distance is precise, such that it cannot determine whether there was insufficient play.
 - iii) Dr Andrew's evidence that he checked the bumper for play and confirmed it was without tension should be accepted.
 - iv) Dr Andrew's evidence as to the check he undertook was not challenged and the challenge that he 'left very little play in the tube' is consistent with the required standard of care.
 - It is implausible that someone with Dr Andrew's considerable experience would have abandoned his usual approach of fitting the bumper allowing for play by reference to feel and by checking the appearance and manipulating the PEG tube in the operation room and procedure room.
- 156. The defendant's submission that Dr Andrew was not adequately challenged on his evidence is unfair. Mr Bradley put to Dr Andrew that he had failed to exercise reasonable care and skill such that he had left tension between the bumpers. Dr Andrew disagreed. [Day 2 transcript, p108] The proposition was again put to Dr Andrew at the end of cross-examination. [Day 2 transcript, p145] It was also put to Dr Andrew that there was no note to suggest he had checked whether there was any tension at the end of the procedure. [Day 2 transcript, p142] I am more than satisfied that the claimant's case was put to Dr Andrew and he had an opportunity to answer it.
- 157. I am not persuaded by the defendant's submission that tension is implausible on the basis that Dr Andrew has considerable experience. Even the most experienced of practitioners can make mistakes on occasion.
- 158. The finding of fact that the skin-to-gastric lumen distance was around 2.5 cm, with

[2024]EWHC 3156 (KB)
the outer bumper placed at around 2.5 cm, does not in itself mean that there was insufficient play as the distances are approximations only and it is apparent

from the expert evidence that very small amounts (measured in millimetres) of 'play' can be sufficient. The finding does however make it much more likely that excessive tension occurred than if the skin-to-gastric lumen distance had been only around 1 cm. Whilst not determinative on its own, the factual finding is a material factor to be taken into account when considering whether there was excessive tension in this case.

- 159. The determination of breach of duty rests largely with an assessment of the credibility of Dr Andrew's evidence. For the reasons already discussed in paragraphs 133-135 of this judgment, there are significant concerns about the reliability of Dr Andrew's recollection of events. His written evidence to the effect that *"there was a distance of 1.5 cm between the external bumper and skin surface"* is demonstrably incorrect, on his own oral evidence as to the skin- to-gastric lumen distance at the conclusion of the procedure. The problems surrounding the reliability of Dr Andrew's recollections taint his evidence that there was no tension between the bumpers when he concluded and checked the procedure. The defendant's suggested approach to this issue would amount to a cherry-picking of Dr Andrew's evidence as to a lack of tension in circumstances where the court has rejected other material parts of his evidence.
- 160. The combination of the concerns as to the reliability of Dr Andrew's recollection and the finding that the skin-to-gastric lumen distance and bumper- to-bumper were both around 2.5 cm, means that I am persuaded that the claimant has established on the balance of probabilities that Dr Andrew breached the required standard of care by leaving the claimant with a PEG that was fitted with too much tension.

Causation

The parties' cases on causation

- 161. The claimant's case on causation was pleaded and remains that the excessive tension between the PEG bumpers caused tissue to die and the contents of the stomach to escape, leading to peritonitis and sepsis.
- 162. The defendant's case on causation has developed over time. That evolution requires consideration as the claimant contends that the defendant should not be permitted to argue a case on causation which, it submits, has not been pleaded.
 - i) The original Defence, dated 23 March 2023, denied that the tissue breakdown was caused by tension between the bumpers and averred a positive case to the effect that it was likely that the tissue breakdown was instead caused or contributed to by one or more of (1) manipulation of the PEG by the claimant when awake, (2) pressure placed on the PEG by the claimant when awake or asleep and (3) poor wound healing arising from the claimant's condition, nutritional status and use of naproxen.
 - ii) Mr Wyman, the defendant's general surgeon, prepared his expert report in $P_{\text{age }74}$

[2024] EWHC 3156 (KB) February 2024. He concluded that the cause of the necrosis was uncertain but identified four possible contributing factors as being (1)

poor wounding healing as a result of the claimant's nutritional condition, (2) use of non-steroidal medication delaying wound healing, (3) pressure placed on the PEG when the claimant was asleep, (4) impaired gastric perfusion if the stomach was distended by enteral feed or the weight of a feed pulled the stomach down on the internal bumper. Mr Wyman's factors (1) – (3) had been pleaded in the Defence but (4) had not.

- iii) The general surgeon experts prepared their joint statement in May 2024. They agreed that excessive tension was a possible cause of necrosis although disagreed as to the likelihood of that occurring if the court found the skin-togastric lumen distance to be 2.5 cm. Mr Wyman's position on possible alternative causes shifted and both experts agreed that manipulation of the PEG, pressure placed on the PEG and poor wound healing (i.e. the three positive factors pleaded in the Defence) were unlikely to have caused the necrosis.
- iv) By Amended Defence, dated 6 September 2024 and thus 10 days before trial, the defendant amended its statement of case to remove reference to the three alternative positive causes identified in the original Defence. Instead, the defendant pleaded simply that the breakdown of tissue and so leak of stomach contents into the abdomen *"occurred despite the exercise of reasonable care and skill".* It was pleaded that a breakdown of tissue and leak of stomach contents was a rare but recognised complication of the insertion of the PEG that may occur with appropriate care and *"it is likely that is what occurred in the claimant's case."*
- v) In closing submissions, the defendant submitted that the claimant could not establish causation on the basis that there were other possible causes of the necrosis including infection; gastric content coming into contact with the PEG wound; tension caused by the PEG tube being larger than the hole made by the trocar; or tension caused by feed being retained in the stomach causing the stomach to pull against the internal bumper (together 'the Alternative Theses'). The defendant's written closing submissions provided a detailed analysis of the oral evidence given by the general surgeons and the gastroenterologist experts insofar as such evidence touched on the Alternative Theses.
- 163. The claimant submitted in closing that the defendant was seeking to postulate the Alternative Theses in circumstances where they had not been pleaded in the Amended Defence. Mr Bradley submitted it would be unfair and wrong for the court to permit the claimant to rely on the unpleaded Alternative Theses which had been raised for the first time in the witness box in circumstances where:
 - The experts were deprived of the opportunity to discuss the Alternative Theses at the joint statement stage.

[2024] EWHC 3156 (KB)
 ii) Mr Wyman gave evidence and advanced the theories after the claimant's expert, Mr Sarela, had already given his evidence.

- iii) The claimant has been deprived of the opportunity to investigate and explore the merits of the Alternative Theses through further investigations, such as literature review.
- 164. Mr Barnes did not accept that the defendant was trying to run a different case to that pleaded, although did make some concession in his oral closing submissions to the effect that it could be said that the Amended Defence could have been more detailed. No application was made for permission to further amend the Amended Defence.
- 165. The importance of statements of case has been emphasised in a number of recent Court of Appeal decisions. In *Satyam Enterprises Ltd v Burton & another* [2021] EWCA Civ 287 Nugee LJ, in explaining why a party was correct not to seek to uphold a finding on a basis that had not been pleaded, said at [35]:

"This is not therefore a case, as sometimes happens, where one or other of the parties seeks to run a different case at trial from that pleaded. That itself is unsatisfactory and can cause difficulties, as has been said recently by this Court more than once: see UK Learning Academy Ltd v Secretary of State for Education [2020] EWCA Civ 370 at [47] per David Richards LJ where he said that statements of case play a critical role in civil litigation which should not be diminished, and Dhillon v Barclays Bank plc [2020] EWCA Civ 619 at [19] per Coulson LJ where he said that it was too often the case that the pleadings become forgotten as time goes on and the trial becomes something of a free-for-all. As both judges say, the reason why it is important for a party who wants to run a particular case to plead it is so that the parties can know the issues which need to be addressed in evidence and submissions, and the Court can know what issues it is being asked to decide. That is not to encourage the taking of purely technical pleading points, and a trial judge can always permit a departure from a pleaded case where it is just to do so (although even in such a case it is good practice for the pleading to be amended); in practice the other party often, sensibly, does not take the point, but in any case where such a departure might cause prejudice he is entitled to insist on a formal application to amend being made: Loveridge v Healey [2004] EWCA Civ 173 at [23] per Lord Phillips MR."

166. Nugee LJ cited with approval at [36] an extract from *Al-Medenni v Mars UK Ltd*[2005] EWCA Civ 1041 where Dyson LJ at [21] stated:

"In my view the judge was not entitled to find for the claimant on the basis of the third man theory. It is fundamental to our adversarial system of justice that the parties should clearly identify the issues that arise in the litigation, so that each has the opportunity of responding to the points made by the other. The function of the judge is to adjudicate on those issues alone..." [2024] EWHC 3156 (KB)
 167. In Ali v Dinc [2022] EWCA Civ 34 Birss LJ considered the principles in Al-Medenni and Satyam Enterprises, adding at [25] the following:

"To these statements of principle I wish only to add the following. These problems are all concerned with the interests of justice and, in particular, with circumstances which cause prejudice to the losing party. The common sort of prejudice which is to be avoided is that a new point has arisen in such a way that the losing party was not given a proper chance to call evidence or ask questions which could have addressed it. That is why the function performed by pleadings, lists of issues and so on, which is to give notice of and define the issues, is an important one; but is also why a judge can always permit a departure from a formally defined case where it is just to do so. It is also why the judge's function is to try the issues the parties have raised before them, rather than to reach a conclusion on the basis of a theory which never formed part of either party's case. By placing the emphasis on prejudice, the point I am making is that the modern approach to the definition of the issues requires judges to adopt a pragmatic approach in line with the overriding objective and not seek to be governed by unnecessary formality, provided always that it is just not to do so."

- 168. The manner in which the defendant's case has evolved troubles me. As *Al-Medenni, Satyam Enterprises* and *Ali* make clear, statements of case play an essential role in civil litigation. They ensure that the parties are on an equal footing and know, well in advance of the evidence being heard, which issues need to be addressed and what evidence they may wish to garner in support of their case. The importance of the content of statements of case explains why, in this case, the general surgeon experts were asked in express terms by the parties' solicitors to address, at questions 6.3 - 6.5of their joint statement, the three theses advanced by the defendant in its original Defence.
- 169. The Alternative Theses pursued by the defendant in closing were not foreshadowed in the Amended Defence. This is not a technical pleading point. The defendant's closing position advances a variety of positive theses that are materially different from its pleaded case that the necrosis was simply an unidentified rare but recognised complication. The defendant's presentation of its defence has put the claimant at a significant disadvantage:
 - i) The general surgeon and gastroenterology experts did not have the opportunity to reflect on and discuss the Alternative Theses at the joint statement stage. The process of preparing a joint statement, away from the pressure of the witness box, is an important part of the evidential process. Following discussions with an expert colleague, experts may and often do change their views or narrow issues. Indeed, that happened in this case when Mr Wyman abandoned the theses taken from his original report and pleaded in the Defence. Had the defendant made a timely application to further amend its statement of case to advance the Alternative Theses, a further joint

statement would likely have been obtained to address the same. The defendant's approach has deprived the claimant of the opportunity for Mr Sarela to discuss the theses with Mr Wyman at a joint meeting. If that had occurred, it may once again have

resulted in Mr Wyman changing his opinion following discussion and considered reflection.

- ii) The Alternative Theses first started to be ventilated in the cross- examination of Mr Sarela on day 3 of the trial. Mr Wyman had touched on the notion of impaired gastric tissue perfusion if the stomach was distended in the briefest of terms in his original report but the theory was not advanced in the Defence and the experts were not asked to consider it in the agenda set for the joint meeting. Mr Wyman did not raise any of the other Alternative Theses in his written report. (The defendant's gastroenterologist, Dr Bird, did not raise any of the Alternative Theses in his report.) Mr Sarela, although providing an impressive and considered analysis of the questions, was undoubtedly at a disadvantage when cross-examined about these matters. He had no time for considered reflection or further investigation of any relevant literature. Prof Gilmore found himself in a similar position.
- iii) Mr Wyman gave his oral evidence after Mr Sarela's evidence had concluded. This only exacerbated the claimant's disadvantage as the claimant's counsel was not hitherto aware from the written expert reports that Mr Wyman was postulating new theses.
- iv) The claimant's legal representatives were deprived of the ability more generally to investigate and explore the merits of the Alternative Theses as part of their trial preparation.
- 170. In my judgment, the prejudice caused to the claimant arising from the defendant's failure to particularise the Alternative Theses in the statement of case means that it would not be just for the defendant to be permitted to now advance the new theses. The question of causation will thus be determined without reference to the Alternative Theses.

Proof of causation (without the Alternative Theses)

- 171. The burden of proof rests on the claimant to prove, on the balance of probabilities, that the undue tension between the PEG bumpers caused the necrosis. It is insufficient if that negligence is a possible but not the probable cause of the necrosis. (Per *Gregg v Scott*). The fact that the defendant has not been permitted to rely on the Alternative Theses does not, of itself, mean that the negligent tension was the effective cause. It does not turn the case into one of res ipsa loquitur nor reverse the burden of proof. The court has to stand back and look at all the evidence and determine whether, on the balance of probabilities, the negligent tension is proven to be the effective cause. The lack of an alternative plausible explanation is however a factor that can be taken into account. (Per *O'Connor v Pennine Acute).*
- 172. The following expert evidence is material when assessing whether the claimant can

HHJ Emma Kelly

[2024] EWHC 3156 (KB) prove on the balance of probabilities that the negligent excessive tension caused the necrosis:

- Mr Sarela and Mr Wyman agreed in their joint statement that excessive tension between the bumpers was a possible source of necrosis. A possibility rather than probability will not, of course, suffice.
- ii) Mr Sarela told the court in re-examination that he *"cannot conceive another cause for necrosis other than excessive tension."*
- iii) Mr Wyman accepted in cross-examination that, if the court were to accept there was excessive tension, the likely cause of the necrosis was excessive tension *"but you have to think about where the tension might be coming from..."* and he postulated other causes of tension which form the discounted Alternative Theses.
- iv) Prof Gilmore was asked in cross-examination whether he was prepared to comment on causation or wished to defer to the surgeons. He indicated he was able to comment and stated *"he could conceive of no other credible mechanism"* other than tension being caused by the bumpers being too close together.
- v) Dr Bird accepted that if the court found there was undue tension, such would be *"the leading cause"* of the necrosis.
- 173. The expert evidence has to be considered within the wider factual matrix of the claim. The court has the benefit of being provided with both the manufacturer's instruction booklet and a guidance video for the Freka PEG device. The risk of necrosis from placing the outer bumper with excessive tension is highlighted as an identified risk. It is noteworthy that no other potential cause of necrosis is highlighted in the manufacturer's literature.
 - i) The audio on the video states: *"Tighten the tube until a slight resistance is felt without exerting excessive pull. Special care should be taken to avoid necrosis."*
 - ii) The instruction booklet has the following wording in bold type:

"Important!

The tube should remain under moderate tension for 24 hours to promote good adaptation of the stomach wall to the abdominal wall. After that, the tube should be loosened. For further securing, leave 5-10mm additional space. Do not pull the tube too hard on the outside, otherwise pressure necrosis can occur."

The notion that excessive tension from the bumpers is a recognised cause of necrosis is also picked up in academic literature specific to the positioning of PEG devices. The paper by Best, referred to by Mr Wyman, states: *"ensure that the fixation device"*

[2024] EWHC 3156 (KB) is neither too tight, which would increase the risk of possible tissue necrosis and ulceration.."

- 175. The clinical note produced by Sian Davies, the surgeon operating on the claimant on 24 March 2016 on admission to Queen's Hospital, noted: "Necrosis around gastrostomy site due to position of PEG being too high (positioned almost to fundus) resulting in tension at gastrostomy site." Whilst the claimant accepts that the positioning of the PEG was not too high, it is nonetheless of note that the surgeon attributed the necrosis to tension.
- 176. Mr Sarela and Prof Gilmore's evidence to the effect that they could not conceive of any other cause for the necrosis other than excessive tension is powerful. They each gave evidence objectively and provided reasoned explanations when cross-examined about the Alternative Theses, in circumstances where the issues had not been foreshadowed in the pleadings, and made concessions to theoretical possibilities. I did not form the opinion they were blinkered in their approach to causation. The absence of any alternative plausible explanation (the Alternative Theses not being taken into account) is a factor that adds weight to the claimant's experts' opinion. The fact that the manufacturer of the Freka PEG device and academic literature specifically highlight the risk of necrosis from the over-tightening of the PEG tube further supports the cogency of the claimant's case. Taken in the round, and remembering this is a case in which there was undue tension between the bumpers, the evidence points overwhelmingly to the probable cause of the necrosis as being that excessive tension.

Proof of causation (taking into account the Alternative Theses)

- 177. For the sake of completeness and in the event I am incorrect as to my decision to exclude the Alternative Theses from consideration, I will address the position had those theses been taken into account. In short, my decision on proof of causation would have been the same. The Alternative Theses postulated were fanciful as opposed to plausible alternative causes. The absence of any plausible other causes would not, in itself, have been sufficient to establish causation but it is a material factor when assessing the evidence as a whole. I would still have been persuaded that the undue tension between the bumpers was, on the balance of probabilities, the cause of the necrosis for the brief reasons discussed below.
- 178. The manner in which evidence as to the Alternative Theses came before the court is relevant. The expert evidence started on day 3 of the trial with the general surgeons first to give evidence. The claimant's Mr Sarela was the first expert to give oral evidence. It is worth remembering that at this stage Mr Wyman had not yet given his oral evidence postulating the Alternative Theses.
 - Mr Sarla viewed references in academic literature to periostomal leakage as referring to a minor complication whereby there was leakage onto the outside skin rather than within the abdominal cavity.
 - ii) He acknowledged there was a risk of infection at any point along the track

but whether it resulted in the death of tissue would depend on the nature of the infection.

iii) He acknowledged that feed or stomach contents could leak from the stomach into the abdomen. He did not accept that would cause necrosis and death of tissue because it would be necrosis that caused leakage not the other way round. He could not postulate a mechanism whereby necrosis would happen.

- iv) He acknowledged that there could be limited tissue trauma by pulling the PEG tube through the smaller hole made by the trocar but could not postulate a mechanism whereby that caused necrosis.
- 179. In summary, it was apparent that Mr Sarela viewed the Alternative Theses as, at their highest, theoretical possibilities rather than plausible alternative causes.
- 180. Mr Wyman gave his evidence immediately after Mr Sarela. He introduced theories not previously addressed in his written report and joint statement.
 - i) He postulated that tension could come from other causes such as:
 - i) Feed distending the stomach and putting tension on the internal flange on the gastric wall.
 - ii) The radial, outward, tension from the tube itself as it passes through the stomach wall.
 - He also postulated that there may have been leakage of feed or gastric content around the side of the tube as it exited the stomach which caused necrosis of the stomach.
- 181. It is apparent from paragraph 4.1 of Mr Wyman's report from February 2024 that he was giving his opinion on the assumption that there was no excessive tension between the internal and external bumpers. That assumption proved mis-founded but likely influenced his approach to the case in seeking to suggest causes that were not based on the factual position as has been found. There are difficulties with Mr Wyman's evidence as to the Alternative Theses:
 - i) Mr Wyman dealt with causation in express terms in his first report. Whilst postulating other theories since abandoned, he did not refer to radial tension from the tube or leakage around the side of the tube. That these were mentioned by him for the first time in the witness box, when he had months to contemplate the position, undermines the cogency of that evidence to a very significant extent. He did make brief reference in his report to the possible consequences of a distended stomach putting pressure on the internal bumper. It is however telling that the defendant did not consider it an important enough issue to include in the Defence. Mr Wyman himself did not consider it of sufficient importance to warrant mention in the joint statement when he discussed the case with Mr Sarela.
 - ii) Mr Wyman's suggestions that the necrosis could have been caused by

tension arising from a distended stomach or radial tension from the tube itself are not reported in the academic literature put before the court.

- iii) His theory that there may have been leakage around the side of the tube was undermined by the defendant's gastroenterologist, Dr Bird, who initially told the court that leaking was associated with there being too much PEG tube rather than there being too little. Later in cross- examination, Dr Bird agreed with the proposition that, if there was hardly any excessive tube, the possibility of leakage was close to fanciful. In re-examination, he changed his mind and stated there was a risk of leakage however the tube was set. Dr Bird's change of evidence of itself undermined his credibility on this issue. Furthermore, the explanation he gave as to how such leakage occurred pointed to it being a risk associated with excessive tubing rather than too tight a fitting. He attributed leakage to the gastric wall not being 'sandwiched' to the abdominal wall. That would be consistent with there being an excess of PEG tube, as slack could mean that the abdominal wall and gastric wall were not pulled together. However, if there was excessive tension between the bumpers, as here, the structures would have been 'sandwiched' together. In short, Dr Bird's initial reaction that that the risk leakage without excessive tubing is fanciful is far more credible.
- 182. Prof Gilmore was the first of the gastroenterologists to give evidence on day 4 of the trial. The general tenor of his evidence that the Alternative Theories put to him in cross-examination were at best theoretical rather than plausible. For example, he described the risk of necrosis from pulling the PEG tube through the trocar hole as theoretical and not something he had seen in over 1,000 cases. He viewed the theory of leaking stomach acid as being unlikely to be a true hypothesis, and the risk of infection from the PEG entering the stomach as being a theoretical risk but that the chain of causation was getting very long. Prof Gilmore, as with Mr Sarela, dealt admirably with questions on the new theses and remained open-minded but quite clear that he did not view the theories as plausible.
- 183. In summary, Mr Wyman's late presentation of the Alternative Theories undermined the cogency of his evidence and Mr Sarlea and Prof Gilmore were the far more credible witnesses. For the reasons discussed above, the Alternative Theses were not plausible explanations for the claimant's necrosis. In the absence of any plausible causes, the court is left with the evidence as to the effect of the tension caused by breach of duty. For the reasons discussed in paragraphs 172-176 above, the claimant would still have been able to prove on the balance of probabilities that the breach of duty was the effective cause of the necrosis.

Acceleration

- 184. The defendant put the question of acceleration in issue at paragraph 15(b) of the Amended Defence pleading that the causative effect of the peritonitis and sepsis was limited to a 6-year acceleration of the claimant's pre-existing deteriorating condition.
- 185. In closing submissions, the claimant no longer sought to advance a case based on Dr

HHJ Emma Kelly

[2024] EWHC 3156 (KB) Bavikatte's evidence. Rather, it was submitted that the issue could be determined on

the facts by reference to what is asserted to be a concession by

Dr Bowler as to the likelihood of the claimant's retaining mobility into her mid to late 50s if she was ambulant indoors, with a bit of assistance, immediately before the PEG procedure.

- 186. The defendant relies on the evidence of Dr Bowler as to acceleration. Mr Barnes submitted that, if the evidence in the medical records was accepted, then the only evidence on the issue before the court was that of Dr Bowler such that the court should accept his opinion as to acceleration.
- 187. The task of any medical practitioner being asked to give an expert opinion on what would, on the balance of probabilities, have happened to an individual in the future but for an index event is always very difficult. Medicine is not a precise science. Where, as was the case here, the expert is being asked to comment in circumstances where there is a factual dispute as to the baseline to be adopted at the date of the index event, that process is made even more difficult. The findings of fact as to the claimant's level of functioning in March 2016 are set out in paragraph 150 above. Dr Bowler did not know what those findings would be at the point he wrote his report or gave oral evidence but it is nonetheless necessary to consider his evidence against the subsequent findings of fact.
- 188. Dr Bowler's report placed heavy reliance on the medical records. His conclusion as to the claimant's mobility in 2016 at para. 6.3.2 of his report was that she "was already profoundly impaired...[and] in so far as she retained mobility at all, there would have been further deterioration." Dr Bowler confirmed in this oral evidence that he had formed the view that the claimant's mobility in 2016 was "very low indeed" and that she was "immobile in the sense of locomotion" by which he meant her ability to "ambulate and transfer". His assessment was more negative than the subsequent findings of fact which have determined that the claimant had remained ambulant, with assistance, over short distances in the home. To that extent, Dr Bowler was too pessimistic in his assessment of pre-accident mobility. Dr Bowler concluded, at para. 6.3.3, that "if the evolving impairment of mobility noted above is correct, then [the *claimant] could not have been toileting independently in 2016".* This assessment is slightly but not significantly more negative than the court's finding that the claimant was largely incontinent of faeces and urine, but retained some daytime control of urine, albeit mobilising to the toilet would have been with assistance. Dr Bowler concluded, at para. 6.3.6, "that there was a well-established requirement for a PEG prior to the peritonitis." His assessment accords with the findings of fact. In short, the baseline Dr Bowler adopted in his report was slightly more negative as to the claimant's level of functioning as determined but not significantly so.
- 189. In cross-examination, Dr Bowler was asked to give his opinion on the likely progression of the claimant assuming a particular baseline functionality. The following exchange took place:

Mr Bradley: "Going back to our case, it is entirely feasible that an adult in

their mid-20s who, in broad terms on the evidence that the court heard from the claimant's side, was ambulant indoors, perhaps with a bit of assistance either for reassurance or otherwise, holding a hand walking around the home, who was able to walk to the carer's car, but that who was wheelchair dependant over longer distance, would retain that sort of mobility to their mid to late 50s but would require hoisting by aged 60. That is Dr Bavikatte's view as to likely progression in those circumstances?"

Dr Bowler: "Yes, on those facts that would be approximately my interpretation as well."

Mr Bradley: *"That is the pattern you would often see in a cerebral palsy patient with that sort of input."*

Dr Bowler: "It is."

- 190. The findings of fact as to the claimant's mobility are a close approximation of the circumstances outlined in Mr Bradley's question although some of the limitations were slightly more pronounced than Mr Bradley envisaged. Assistance by way of hand holding and encouragement for short distances indoors would have been the norm there was no 'perhaps' about it. There were also some 'bad days' when she was not able to walk to the carer's car. Nonetheless, Dr Bowler's evidence indicates that one would expect the claimant to retain, in approximate terms, that sort of mobility to her mid to late 50s but a need for hoisting by age 60. As such, the claimant can establish on the balance of probabilities that the deterioration in her mobility after the PEG procedure is not limited to a 6-year acceleration period. The claimant's mobility would have deteriorated in any event but in a manner that allowed her some indoor ambulation with assistance to her mid to late 50s, with hoisting by the age of 60.
- 191. Dr Bowler's opinion as to future mobility is important as he based his assessment of the likely acceleration of other aspects of functioning on his findings as to mobility. He explained his approach to determining acceleration to the court in the following way:

Dr Bowler: "...I would have to advise the court that estimating something like this is necessarily very approximately [sic] with very wide margins of error and in estimating those, I have taken an initial interpretation on the most clearly defined, which, if I remember my report correctly, was on mobility – and then in interpretation of the other matters, I have asked myself: is there any reason to suppose that advancement would be any different, and if they fall broadly within the same wide parameters, I have taken the view that they would approximately be the same."

192. Dr Bowler, at para. 6.3.3, considered that the claimant would have required a catheter in any event within 6 years and that this issue *"would have been dependent on and changed to some extent pari passu with mobility.."* The link between continence and mobility is self-evident, if an individual cannot ambulate to the toilet,

HHJ Emma Kelly [2024] EWHC 3156 (KB)

it makes continence very much more difficult to manage. The finding of fact is to the effect that the claimant had only a low level of continence before the procedure. The claimant's closing submissions accepted

that "*her function was also likely deteriorating.*" The difficulty for the claimant on the issue of continence is that, even if the claimant retained mobility with assistance into her mid to late 50s, the court has no evidence before it that her continence would have followed a similar trajectory. Indeed such a position seems unlikely given the claimant's concession that she was likely deteriorating. Unlike on the issue of mobility, Dr Bowler was not asked in cross-examination to comment on the likely progression from a position of limited continence. The burden rests on the claimant to prove her case in respect of any deterioration in her continence. In the absence of any credible expert evidence of her own on this topic, the claimant cannot do so. Dr Bowler's evidence amounts to a concession by the defendant to a 6-year acceleration period in respect of continence issues. I adopt that concession and limit the causation period relevant to continence to 6 years.

- The court has found that the claimant's ability to swallow had deteriorated before 193. the procedure to a point whereby she required a PEG tube for both food and fluid intake reasons albeit the expectation was the PEG would initially supplement rather than wholly remove oral intake. Post-procedure the claimant is completely PEG-fed and has a tracheostomy. Dr Bowler, at para. 6.3.6, concluded that the peritonitis had accelerated a progression to complete intake via a PEG and the need for a tracheostomy by 6 years. He acknowledges in his report that: "It would be unusual for there to be a level of dysphagia so profound as to require a tracheostomy to protect the airway but in [the claimant's] case there is also the issue of her regurgitation which was also developing prior to the peritonitis." In cross-examination, Dr Bowler agreed that very few patients with cerebral palsy end up with tracheostomies even at the end of life and that his main justification for concluding that a tracheostomy would have been required in 6 years was the risk of aspiration, specifically aspiration pneumonia. He accepted there were no signs of aspiration when the videofluoroscopy was undertaken in 2015 but noted that her swallow function was not normal as she was losing weight and unable not take in enough fluid.
- 194. Dr Bowler's conclusion that the claimant is likely to have progressed to requiring complete intake via a PEG in 6 years is logical, indeed he was not challenged on that aspect of his opinion. The claimant's oral intake had been deteriorating and, by March 2016, she had progressed to requiring the PEG procedure for both fluid and food reasons. The overall trajectory of her oral intake was downwards. The claimant has no evidence to counter the defendant's case on this issue and, as with the continence issue, it is appropriate to limit the causation period as regards any oral intake to 6 years.
- 195. Whether the claimant would have required a tracheostomy in any event in 6 years requires separate consideration. Dr Bowler's evidence on this point was challenged in some detail. Aspects of his rationale on this topic troubled me. The evidence is that, in general, very few patients with cerebral palsy need a tracheostomy, even at the end of life. What was it then that made the claimant one of those rare cases that

would have needed a tracheostomy? The 2015 videofluoroscopy report noted that there had been *"ongoing reports of reflux symptoms i.e. small amounts of stomach contents have been seen on her pillow at night"*. Dr Bowler however agreed that the videofluoroscopy revealed no signs of aspiration, the condition he considered the main justification for a tracheostomy. The incidence of chest infections and pneumonia since 2018 provides a tenuous link to the path to an inevitable tracheostomy. The claimant's position by 2018 has to be considered in the context of her having lost her mobility after the peritonitis. That loss of mobility is likely to have had a detrimental effect on her overall general health. Dr Bowler, both in his original report and oral evidence, assumed a lower level of mobility in 2016 than the court has concluded was the case. That is likely to have affected his opinion as to the trajectory regards aspiration. Considering Dr Bowler's evidence in the context of the wider factual matrix, it is not credible that the claimant, who was able to ambulate around the home with assistance and whose recent videofluoroscopy had shown no signs of aspiration, would have ended up with a tracheostomy 6 years later. I thus reject the defendant's case on this point.

- 196. In conclusion, the breach of duty caused:
 - A loss of mobility in circumstances where the claimant's mobility would otherwise have continued to deteriorate but she would have maintained some indoor ambulation with assistance to her mid to late 50s but have required hoisting by the age of 60.
 - ii) An acceleration of the claimant's progression to complete incontinence (from an already low starting point) by 6 years.
 - iii) An acceleration to complete feeding by PEG (from a position of a PEG already being required for some feeding) by 6 years.
 - iv) The need for a tracheostomy.

Conclusion

197. The claimant has proved her case on liability, subject to the conclusions in paragraph196 above as to the extent of causation, and judgment will be entered against the defendant.