NC [2019] EWHC 2488 (QB)

Case No: B90BM359

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

Birmingham District Registry
33 Bull St, Birmingham B4 6DS

Date: 12 September 2019

Before:

JUDGE ALLEN
SITTING AS A DEPUTY HIGH COURT JUDGE

Between:

Salina Rai (neé Kalair)	**Claimant**
- and -	
University Hospitals Coventry and Warwickshire NHS Trust	**Defendant**

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Mr J Coughlan (instructed by **Irwin Mitchell LLP**) for the **Claimant**
Ms J Mishcon (instructed by **Messrs Bevan Brittan LLP**) for the **Defendant**

Hearing dates: 17 June 2019- 20 June 2019

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JUDGMENT

JUDGE ALLEN:

1. This is a clinical negligence claim arising as a consequence of a laparoscopic sleeve gastrectomy performed by employees of the Defendant on the Claimant on 16 February 2013. Quantum has been agreed, and therefore I am concerned with issues of liability only. It was alleged that as a result of the Defendant's failure to diagnose and manage a post-operative staple line leak, the Claimant endured avoidable suffering until a diagnosis was made on 11 March 2013, by which time she was suffering from severe abdominal sepsis. Thereafter she suffered the avoidable effects of a persistent fistula and the complications of complex and lengthy treatment and is left with residual physical and psychological injury.

2. I heard evidence from the Claimant, her mother, the surgeons Mr Menon and Mr Fraser and the experts Mr Fiennes and Professor McMahon. In the interests of providing a briefer judgment I have placed the summary of the oral evidence in annexes.

The Claimant

3. In her witness statement the Claimant referred to the weight problems that she had had and the suggestion made to her that it might be possible to have a laparoscopic sleeve gastrectomy. She attended the hospital on 16 February 2013 for surgery. She said that when she woke up after the operation she was in a lot of pain. She was given morphine for the pain and that allowed her to go to sleep until the 17th. She said that on the 17th she tried to have sips of water but felt really sick and would vomit it back up again and could not keep anything

down and was also in a lot of pain. Apart from that she did not remember much about that day as she was in so much pain.

4. She said that on 18 February she was still being sick. She remembered seeing Dr Fraser, who had carried out the surgery and being told the operation was a success and she needed to try and eat something before she was able to go home. She remembered telling him that she did not feel well and was in pain. She was given a yoghurt to eat, the first thing she had eaten since the surgery and had one spoonful and immediately vomited it back up. She said that she was unable to drink anything because it hurt when she did so and her lips were extremely dry.

5. She was told she was being discharged home and her mother said she was shocked that they were talking about discharging her when she could not eat. She said she was told that she would feel much better once she was at home in her own environment. She did not remember being offered any more food, and certainly did not eat anything. She said she was sent home that afternoon despite being unable to eat or drink anything and remembered saying she was still not able to eat or drink and was told she would be fine once she was at home and eating again and if she did not feel any better she should speak to her GP.

6. She went to her parents' house. She was concerned on the next day, the 19th, that she was not getting any better. Her mother brought her a yoghurt but she vomited it straight back. She said she had not eaten or drunk anything since the surgery and was in a lot of pain.

7. She went back to the hospital on 20 February. Staff tried to get her to eat but she could not and the nurse commented that her lips were very dry and she said it was because she had not drunk anything since the surgery. Her mother told the doctor she was really worried because she had not been eating or drinking and the doctor said she should have little bits at a time. She was given some liquid to drink which she was told was some sort of test and was kept in for two days and discharged home on 22 February.

8. She said she was still unable to eat or drink and was still in a lot of pain over the next few days. She saw her GP on 25 February and spoke to the GP again on 1 March. She went back to hospital on 3 March 2013 and was kept in until 5 March. There was talk of her having a CT scan but that did not happen.

9. She was admitted back to hospital on 10 March 2013 as she had been being sick all weekend. She was in hospital for several weeks and ultimately had further surgery on 31 March 2013. An oesophageal stent was inserted on 17 April. She was discharged on 29 April 2013, continued to suffer from pain and vomiting and subsequently it was learned on 13 May 2013 that she had a pulmonary embolism. She remained unwell and went back to hospital on 11 June 2013 and on the following day had a procedure to reposition the stent. She subsequently suffered from sepsis and she described the difficulties she experienced subsequently.

10. I do not set out the detail of those subsequent events since the claim is focused essentially on the events of mid-February 2013.

Mrs Nirmla Kalair

11. The next witness was the Claimant's mother Mrs Nirmla Kalair.

12. In her statement she said that she with other family members visited the Claimant after her surgery and they could tell how much pain she was in. They were told by the nurses this amount of pain was to be expected following the surgery.

13. She returned to the hospital the next day to see the Claimant, who was in constant pain. She was unable to eat or drink which was concerning and also vomited on a number of occasions. Over the course of the next couple of days the Claimant was only able to drink very small sips of water through a straw and was unable to eat anything and was in a lot of pain and looked very weak. There were several occasions when the Claimant was in hospital that she screamed with pain. The doctors kept saying that medically she was fine, which they could clearly see was not the case.

14. She was discharged on the 18th. She was very worried about the Claimant being discharged when she was still so poorly and she had told the doctors she was unable to eat and could hardly drink and they had said everything was normal and in time she would be able to eat. By the time of discharge she was much weaker than she had been immediately after her surgery as she had been unable to eat.

15. After discharge the Claimant remained in a lot of pain. She had initially been given intravenous painkillers while in hospital but was unable to take them when she went home. She had tried to feed her and if she ate at all it would be the tiniest amount of food and half of the time she was sick after eating even a little food. She was sent back to hospital following a visit to the GP, after a

couple of days. She was again discharged after a couple of days and remained very unwell and eventually went back to hospital several weeks later and she was given a scan and they were told there was a leak. She then referred to subsequent treatment that the Claimant had.

Mr Vinod Menon

16. Mr Vinod Menon then gave evidence. He is a Consultant General and Upper Gastrointestinal Surgeon employed by the Defendant. He has been a consultant since September 2002.

17. In his statement he said he was one of the Claimant's treating surgeons. He had assisted Mr Fraser in the surgery and was involved in the Claimant's care before and after the surgery.

18. He said the surgery was performed by him and by Mr Fraser with him assisting and it was a little awkward because of the Claimant's size but this was not unusual with bariatric patients and the surgery was completed with no particular difficulty.

19. The Claimant was monitored closely and observations were taken at regular intervals that night and over the next two days until her discharge. There was nothing particularly unusual in her post-operative progress that would have given him or any of the other doctors reason to be worried or suspect a potential leak. She had full blood tests every day and the results were all completely

normal. Whilst it was true that she had some nausea and some difficulty in keeping fluids down that was not unusual after this type of surgery. The surgery significantly reduces the size of the stomach and added to that there would be swelling from the trauma of the surgery itself, so it was not surprising that some patients had difficulty initially. She also reported some pain but nothing beyond the range that would be expected after this surgery.

20. At 8.30 on 17 February the nurses recorded that the Claimant had a settled night and was having occasional sips of water and there were no new concerns. He had reviewed her on the afternoon of 17 February and gave instructions for a trial without catheter and that she could have free fluids and start a liquid diet from the following morning.

21. She was reviewed by Dr El-Sayed and Dr Oldroyd [his name is misspelt in the witness statement but was corrected at the hearing]. They reviewed the Claimant at 10.30 on 18 February. She was complaining of pain but had only paracetamol and was still having difficulty in keeping down fluids, but she was sitting out of bed and her abdomen was soft and non-tender on examination and they felt she was well.

22. Mr McCullough had seen her at 12 o' clock and he noted she was stable with good urine output but still having difficulty tolerating water.

23. Mr Fraser had seen her during his ward round on the afternoon of the 18th. She had complained of being unable to keep down water so he told the nurses to give her yoghurt or soup. Her observations and blood test results were all within expected limits so the plan was for her to go home that afternoon. It was noted at 2 o'clock that pain relief had been given with good effect and that she

had eaten some lunch without vomiting. She was discharged later that day with a supply of medication to be followed up in Mr Menon's outpatient clinic.

24. The Claimant returned to hospital on 20 February. She was no longer vomiting but was complaining of pain on swallowing which made her apprehensive about drinking and she seemed to be mildly dehydrated.

25. She was reviewed at 2000 hours. She was swallowing liquids but complaining of epigastric pain after swallowing. This was not getting any worse but it was not going away and she did not have any other symptoms.

26. She was reviewed on the morning of the 21st. The Specialist General Surgery Registrar, Mr Ang, had the impression she was well but a water soluble contrast swallow investigation was arranged to rule out any leaks. That was carried out at 11.59 on 21 February, and it was reported that contrast was observed to pass without impediment from the oesophagus into the gastric sleeve and no leak was seen. She was reviewed after that procedure and reviewed again the following morning and was discharged later on, on 22 February. He considered the decision to discharge was reasonable on both the 18 and 22 February.

Mr Ian Fraser

27. The next witness was Mr Ian Fraser, now retired, but at the time of the claim a Consultant General Surgeon employed by the Defendant, having been employed as a Consultant since 1986. He was the operating surgeon in this case, assisted by Mr Menon. He was also involved in the Claimant's follow-up care until her discharge from hospital on 18 February 2013 and again during her admission between 20 and 22 February.

28. In his statement he said that he did not remember any particular difficulty with the operation. The Claimant was subsequently monitored closely and observations taken at intervals throughout the evening after the surgery and night and over the course of the next two days. There were no particularly unusual features in her post-operative course that would cause him any concern. She had some nausea and difficulty tolerating fluids but that was common after this type of surgery. Likewise the pain she experienced was not unusual; different patients' experience of discomfort and immobility could vary after surgery and there was nothing in her presentation that was out of the ordinary or that would cause concern.

29. He noted that she was reviewed by Mr Menon on 17 February and by Dr El-Sayed and Dr Oldroyd on the 18th. He noted that she was complaining of pain but was observed to be only on paracetamol. She said she was having difficulty in keeping down fluids. She was prescribed Diclofenac per rectum for her pain. He noted that she was seen by Mr McCullough on his ward round at noon and was noted to be stable with good urine output but was having difficulty tolerating oral fluids.

30. He saw her during his rounds sometime before 2 o'clock on 18 February. She complained of being unable to keep down water. He instructed the nurses that she could have yoghurt or soup. He did not have any concerns about her progress: her observations and blood test results were all within expected limits. If there had been anything out of the ordinary in her presentation or test results he would not have recommended her discharge. As it was he was entirely satisfied with her progress and said she could be discharged home later that day

so long as she felt well enough. He noted that the nurses at 2 o'clock on 18 February noted that pain relief had been given with good effect and she had eaten some lunch without vomiting.

She was discharged later that day with a supply of medication but was readmitted on the 20th complaining of pain on swallowing which made her apprehensive about drinking and she appeared to be mildly dehydrated. She was seen by the General Surgery Specialist Registrar at 2000 hours on the 20th and it was noted that she was swallowing liquids but complaining of epigastric pain after swallowing which was not worsening but was persistent. A water soluble contrast swallow investigation was carried out at 11.59 on 21 February and the contrast was observed to pass without impediment from the oesophagus into the gastric sleeve and no leak was seen. He agreed with the Consultant Surgeon's plan to discharge her home, on 22nd February, and she was discharged later that afternoon. As regards the readmission between 20 and 22 February he remained satisfied that there was nothing in her presentation then, her blood tests and observations that might have caused him to question the findings of the radiologist or to suspect a leak. There was no reason to find the report of the contrast swallow was anything but reassuring and it would not have been reasonable to request a CT scan, exposing her to radiation, unless there was good reason to do so such as evidence of deterioration in her condition or sepsis. Her symptoms were within the range of post-operative symptoms experienced by some patients after a sleeve gastrectomy as the result of functional adjustment of the gastrointestinal tract and the surgery itself.

Sister Deborah Ursell

31. The next witness was Sister Deborah Ursell (formerly Moore).

32. There was legal argument at the start of the hearing about whether I should permit the Defendant to rely upon her witness statement and to allow her to give oral evidence.

33. In his skeleton argument Mr Coughlan accepted that the trial was not imperilled by this application no matter how it was determined, but it was not agreed that she should be allowed to give evidence given the late stage at which her witness statement was produced, contrary to the timetable set out on 19 February 2018, and the fact that the note was not accepted from the outset of these proceedings. Mr Coughlan sought to rely on what had been said in Wisniewski v Central Manchester Health Authority [1998] PIQR P324, where an adverse inference was drawn from the Defendant declining to call a witness to add necessary weight to a critical record. It was argued also that further witness evidence with regard to the presence of vomit on the bedsheets might have been sought. It was contended that if the statement was admitted, leeway in examination-in-chief would be sought for the evidence of the Claimant and her mother but there was a potential injustice in any event.

34. I ruled that the statement could be allowed in and that Sister Ursell could be permitted to give oral evidence. I did not see that the matter fell within what was said in Wisniewski where it was said that either B, the midwife had negligently failed to inform the doctor, R, of a quick foetal heart beat (tachycardia),or R had negligently failed to attend the mother of the Plaintiff who suffered from athetoid cerebral palsy from birth. R was in Australia and declined to return from there. The statement made no reference to what he

might have done if he had been summoned by B. The judge placed considerable weight on his non-attendance, addressing himself to what R would have done if summoned and to what a hypothetical competent doctor would have done in his place.

35. In contrast in this case I accept what is said on behalf of the Defendant that it was only thought necessary to call Sister Ursell after a letter of 9 May 2019 from the Claimant's solicitor put the Defendant on notice that they intended to invite the court to draw an adverse inference from the failure to call Sister Ursell. There was already in the bundle a note of what she had observed on 18 February and it was a question of it not having been thought necessary to get a witness statement from her and to have her give oral evidence in light of what was already provided as part of the evidence from her in the bundle.

36. It seemed to me upon consideration that the overriding objective was best served in this case by admitting the statement and allowing oral evidence from Sister Ursell. The question of what the Claimant ate or drank if anything on 18 February was a key piece of evidence with regard to breach of duty, and it is not as if there was evidence that took the Claimant by surprise. In fact that note was not accepted in the Particulars of Claim and it did not entail that a witness statement would be provided by Sister Ursell and oral evidence sought. Accordingly, I admitted it into evidence.

37. In her witness statement Sister Ursell (previously Sister Moore) said that at the time of the incident she was a Band 6 Clinical Sister working on the surgical ward. She had reviewed the records and could see from her handwriting that she had completed the daily care plan for the Claimant on the 18th, noting her

heart rate, temperature, blood pressure, respiration, oxygen saturation and MEWS at 10 o'clock and 1400. She could see from the observation chart for 18 February that at 0139 no nausea or vomiting was recorded, at 6.19 there was nausea but no vomiting, at 10.25 there was no nausea or vomiting and at 1415 there was nausea but no vomiting. She said that normally the healthcare assistants completed the observation charts and she would not have recorded the observations at 01.39 or 06.19. She could not say for certain whether or not it was she who recorded the observations at 10.25 or 1415.

38. With regard to the entry at 1400 hours on 18 February and in particular the part reading "has had some lunch and not vomited", she confirmed that this was her writing and her signature and that she had made the entry in the records. She had no specific independent recollection of making the entry but could say that she would not have written that the Claimant had had some lunch and not vomited if she was not satisfied that it was correct and that she would not have been discharged if there was any concern that she was not happy to go home or that she was still vomiting. Her invariable practice would be to ask the patient if she had managed to eat any lunch and how much she had managed. They did not expect patients to be able to eat a great deal after bariatric surgery. They were only allowed small amounts and would only usually be able to manage a small amount of yoghurt or ice-cream. What she had written down could only be because that was what the Claimant had told her when she asked her. If she had said she had only had one spoonful and then vomited she would certainly have recorded that in the records and the Claimant would not have been allowed to go home. She was fairly certain that if the Claimant had been sick she would have known about it. She remembered that she had been very reluctant to get

out of bed so if she had vomited the nurses would have known about it because they would have had to clean it up, remove the bowl or change the bed covers. It was very doubtful that she could have vomited without them knowing about it and if she had then they would have made a note about it. Lunch was usually served around 12 to 12.30. There would be absolutely no reason for her to write that she had not vomited unless she was satisfied that it was correct.

39. Sister Ursell adopted her statement as her examination-in-chief.

Expert Evidence

Mr Alberic Fiennes

40. The next witness was Mr Alberic Fiennes who is an experienced Consultant Surgeon with long experience of and expertise in general, upper digestive and bariatric surgery.

41. In his written evidence Mr Fiennes stated that as the Claimant did not improve on the first post-operative day she would on the balance of probabilities not have been considered fit for discharge on the second day. Appropriate investigation and clinical re-examination would have raised the possibility of early staple-line failure or of a self-contained leak at that stage. Without this failure on the balance of probabilities the intractable fistula would not have developed and the ensuing peritonitis, sepsis and nutritional depletion would not have occurred. There was a failure in the standard of care in not registering that the Claimant had not made proper progress in her recovery, still needed strong analgesia, had an unexplained drop in $Sa0_2$ (it had been 100% on admission), there was no clear explanation for her fluid intolerance: localised oedema of the

staple line, portending failure, should have been on the list of possible explanations.

42. Had she been kept in, the fluid intolerance would have persisted and on the balance of probabilities she would not have improved spontaneously. Imaging investigations would have been undertaken, which might or might not have indicated cause for concern along the upper gastric staple line, but given the recognised significant limits to the sensitivity and specificity of both contrast swallow and CT scan, no responsible bariatric surgeon would have been reassured by negative findings in the face of clinical evidence to the contrary. In a situation where any doubt persisted that imaging accurately reflected the clinically evident or suspected actual process, any responsible bariatric surgeon would reasonably have recognised early laparoscopy with or without methylene blue dye testing as the most accurate reliable investigation. In this case, he considered, such doubt would indeed on the strongest balance of probabilities have applied, leading to early laparoscopy. Early (3-4 days post-operative) repair in the course of that laparoscopy stood a better than even chance of success.

Professor Michael McMahon

43. The next witness was Professor Michael McMahon who is an Emeritus Professor of Surgery at the University of Leeds and a Consultant Surgeon at the Nuffield Health Leeds Hospital having been a Professor of Surgery at the University of Leeds between 1996 and 2007. His was the first surgical team to perform a sleeve gastrectomy as a stand-alone bariatric procedure.

44. In his written evidence Professor McMahon considered that on the first post-operative day observations were within expected limits and in particular there was no tachycardia. It was unusual that 10 mg of morphine was required at 02.30 and 13.00 but the reason for and nature of pain and discomfort were not recorded. He considered that the actions taken on 17 February were reasonable and appropriate. On the second post-operative day the Claimant's observations were within the expected range. The oxygen saturation of 94 or 95% on air was reasonable in the circumstances. He observed the nursing note at 2.00 p.m. of Sister Moore, and considered that it appeared that the Claimant's ability to take fluids orally may have improved as the day went on and she may have found it easier to take things such as yoghurt even though she had difficulty with water. He noted that for the blood tests on 18 February the white blood count was normal and C-reactive protein was reassuringly low. It was unusual that 10 mg of morphine was administered on 10.40; the reason was unclear. He considered that from the standpoint of medical review, nursing review, observations and blood results, the Claimant appeared to be making satisfactory progress and was able to be discharged. The small element of concern, her ability to take oral fluids, appeared to have improved. There was no indication to carry out an investigation for a leak prior to discharge. If a leak test had been carried out at the time of surgery on either a contrast swallow or a CT scan performed prior to discharge, no leak would have been revealed. The contrast swallow carried out subsequently on 21 February showed no leak, and he agreed with the radiologist, Dr Tolan, that it would have been routine surgical practice, as well as radiological practice, to accept the findings of the swallow and not proceed to CT scan.

Conclusions on the Evidence

The Claimant

Professor Michael McMahon

45. Rightly it was not suggested that the Claimant had been dishonest in any respect. At the highest it was put by Ms Mishcon that she was confused as a consequence partly of the pain and other problems she experienced after surgery and also the fact that on several occasions subsequently she returned to the hospital having been sick at home.

46. The Claimant found herself having to contend that the nursing records were wrong in not recording vomiting when she said she had vomited. She also had to contend with the contrast between the pain levels recorded and her evidence that she screamed with pain at times. It is also relevant to note that she did not go to solicitors until some two-and-three-quarter years after the index event. Both she and her mother said they told the nursing staff of her pain and the fact that she was vomiting everything she drank on 17 and 18 February, but the nursing notes do not corroborate this. The nursing records of 17 February record nausea on one occasion but do not tick vomiting, and again nausea is ticked on two occasions on the 18th but vomiting is not recorded. The pain scores for 17 February are 0, 2, 1, 1, 1 and 1. The Claimant did not accept that she had had lunch and not vomited, as contended by Sister Ursell in her note on the day.

47. It is also relevant to note that the evidence is that all the medication given to the Claimant on 18 February was oral medication other than a suppository on one

occasion. She said in oral evidence that she vomited instantaneously when she attempted to swallow water.

48. I see force in the point made by Ms Mishcon that it would be extremely surprising if none of the nurses who gave her her medication would have noticed her vomiting it up again. There is of course an absence of any record of vomiting in the notes. It is also relevant to note the reference in the nursing notes on 18 February to "oral analgesic given with effect". It is further relevant to note that the urea, electrolytes and creatinine levels were normal on 18 February and that is an indication again of adequate hydration.

I consider that the Claimant's evidence has to be seen in the context of the suffering she undoubtedly experienced, then and thereafter, as well as the elapsing of time between the events in question and the time when she provided her written statement and gave her oral evidence. It is also relevant to note the reference in her witness statement to her vomiting straight back up a yoghurt which her mother gave her at home on 19 February. It is entirely possible that this event has been confused with what she says happened on the 18th. In terms of how she gave her evidence, she was clear as to what she thought she recalled and did not accept that her memory was at fault.

The Claimant's Mother Mrs Kalair

49. Mrs Kalair referred to the Claimant vomiting on a number of occasions on the 17th and being unable to eat or drink, only to have very small sips of water through a straw over the next couple of days. On several occasions she screamed with pain. She said she told the doctors that the Claimant was unable

to eat and could hardly drink and that after she had taken her home half the time she was sick after eating even a little food.

50. Again her evidence was provided some years after the events in question and there is again, as Ms Mishcon argued, the possibility of confusion bearing in mind that the Claimant was in and out of hospital on a number of occasions over several months. As Mr Coughlan pointed out, the fact that she did not claim to remember the yoghurt vomit incident is a positive in the sense that she is not inventing evidence, though I see it as no more than a neutral factor rather than being an indicator of reliability. Again her evidence about vomiting and levels of pain has to be seen in the context of the evidence recorded by the hospital staff. Again there is no question of dishonesty in her case but it is contended that her memory is fallible and possibly that there was an element of exaggeration with regard to the screaming with pain.

Mr Menon

51. As was suggested by Mr Coughlan, Mr Menon is not a central witness. It is relevant however to note that he said that if he had been told on 17 February when he saw the Claimant that she was not able to tolerate water without vomiting he would not have ordered her to progress on to free fluids that evening and a liquid diet the following morning. His evidence was perfectly straightforward, and he accepted that there were flaws in the procedures, such as the absence of clinical notes for the 17th.

Mr Fraser

52. Mr Fraser agreed that there needed to be a good trend of good observations prior to discharge and that if there were a new complaint of nausea and vomiting this was not consistent with being "well". He accepted that "something had to change" in order for the Claimant to be allowed home and this his definition of "wellness" included non-dependency on opiate analgesia and tolerating adequate fluids and semi-solids sufficient to maintain physiology. He was content to delegate the decision on discharging the Claimant to the nurses who were very experienced, particularly on the ECU.

Sister Ursell

53. Like the other witnesses there is no question as to the honesty of Sister Ursell. She is clearly an experienced nurse who gave her evidence to the best of her recollection. She noted that she did not recall seeing the Claimant vomit and there was no documented evidence that she had vomited. If she had not deemed her well she would not have discharged her. She did not remember the Claimant being taken to the car in a wheelchair but that was not unusual. She accepted that she could not say for sure that she had observed the Claimant eat lunch and not vomit and that the information might have come to her from a healthcare assistant.

Mr Fiennes

54. Mr Fiennes is clearly a very experienced expert, and his report was carefully constructed and clearly set out. He accepted that he had made a mistake as to whether it was 6.00 a.m. or 6.00 p.m. on the 17th that nausea/vomiting was first recorded, and that there might be a mistake in his chart, but otherwise his evidence demonstrated clear expertise and knowledge.

Professor McMahon

55. Professor McMahon was subjected to detailed criticism by Mr Coughlan. To a certain extent I consider that criticism is merited. His report was not structured in the way in which it would have been ideal, for example setting out all the evidence that he had received, and in particular his omission to refer to the witness statements was surprising. Like Mr Fiennes there was an element in his report of taking the line of the party he was instructed by, and they are both liable to some minor criticism in that regard. There are elements of the medical evidence that were not referred to by Professor McMahon, and that must be a matter of note as well.

56. However he is clearly a very experienced expert with a longstanding interest and expertise in this particular type of surgery. The deficiencies in his report do not, in my view, go to the heart of it. In endeavouring to present an objective picture, he erred in that he failed to take into account and therefore balance into what he had to say about the subjective evidence particularly that of the Claimant and her mother, which was a mistake, and also in failing to take into account and point out the deficiencies in elements of the medical evidence. As a consequence he fell short in fulfilling his duties to the court. As I say, I do not consider the deficiencies in his evidence go to the heart of that evidence though I take them into account in the evaluation of what he had to say in going on, as I do now do, to consider first the issue of breach of duty and second the issue of causation.

Discussion

57. The Claimant's pleaded case on breach of duty is that the respondent failed to heed or adequately act upon the Claimant's persistently high analgesic requirement, dropping oxygen saturation levels, de novo nausea and inability to tolerate food and drink which taken together amounted to a failure to progress as one would have expected following the procedure. It was also claimed to be negligent in that the Defendant failed to investigate for leak prior to discharge and discharged the Claimant rather than keeping her in for further monitoring and investigation. As was suggested in Mr Coughlan's skeleton argument, the case essentially resolves on the court's assessment of whether the Claimant was "well" at the point of the decision to discharge.

58. Mr Fiennes considered that purporting that the Claimant was "well" as noted by the junior doctors, was hard to reconcile with their remark about intolerance of oral fluids and vomiting. He noted Mr McCullough's concern to reorder a re-establishment of intravenous fluids and Mr Fraser's note that the Claimant was intolerant of oral intake. He did not consider it was reasonable to describe the situation as one warranting "no concerns". He considered it was slightly inconsistent to be satisfied with the Claimant's progress yet to sanction discharge "so long as she felt well enough". He also criticised Mr Fraser for not operationalising how to determine "well". There was no clear action or decision making plan for the junior doctors or the nurses. He also, Mr Fiennes thought, appeared to ignore the Claimant's requirement for 15 mg of morphine at 10 o'clock a.m. that day which was documented in the records available to him at the time. He considered that the Claimant was sent home without proper focus on her persistent intolerance of oral fluids, her persistent analgesic needs and her drop in SaO_2. Mr Fraser had not ensured that the conditionality of discharge

was understood and he considered the Claimant was sent home through a careless and haphazard lack of process.

59. In his report Professor McMahon considered that the Claimant appeared to be making satisfactory progress on the 18th and was able to be discharged. He considered that the only small element of concern related to her ability to take oral fluids, but by the time of her discharge this appeared to have improved. He made the point that it was important to appreciate the post-operative progress after sleeve gastrectomy is quite variable. In his opinion the results of the blood investigations were very reassuring and suggested that no complication had developed by the time the Claimant was discharged from hospital on the 18th. In his opinion there was no indication to carry out an investigation for a leak prior to discharge from hospital on 18 February. Not only were the Claimant's observations within the expected post-operative range, but there was no suggestion on the blood tests of a leak . In particular a level of C-reactive protein of 11 mg/L on the second post-operative day strongly suggested that no leakage was present. He considered that there was no reason to keep the Claimant in hospital after 18 February and if she had been kept in hospital for further monitoring and investigation it was probable that she would have been discharged within the next day or two.

60. The picture on 18 February therefore was, looking first at the doctors' notes, at 10.30 a.m. Dr El-Sayed and Dr Oldroyd, two very junior doctors, saw the Claimant. They reviewed the operation note and noted that she was experiencing pain and was only on paracetamol. They noted that she was unable to drink fluids without vomiting. Urine was passed easily and the

bowels were not yet open. On examination she had very mild wound pain and on inspection was well.

61. When the more senior Mr McCullough saw her at around noon he noted that her urine output was good but she was not tolerating oral fluids (water). He described her as being stable. He wanted IVI to be re-established and care to be continued.

62. The Claimant was next seen by Mr Fraser. It appears to have been quite soon after Mr McCullough, and indeed the time listed is prior to Mr McCullough seeing the Claimant but it is I think sufficiently clear from the order in which the notes are set out on the form that he must have seen her after Mr McCullough did. He noted that she was unable to keep water down without vomiting. His plan was for her to go home today if well. He appears not to have thought it necessary for IVI to be re-established.

63. The Claimant's evidence was that she was continuously vomiting and at times crying out with pain and that was essentially the evidence of her mother also.

64. We do not have the fluid balance charts which is unfortunate. We do however have the planned nursing care notes. Sister Ursell (at the time Sister Moore) saw the Claimant at 1400 hours. She noted that the Claimant had been seen by Mr Fraser and was for discharge home that day. Volterol had been given with good effect for pain relief. She could have yoghurt and soup and her clips were for removal ten days after the operation, at the practice nurses. Sister Ursell noted that the Claimant had had some lunch and had not vomited and analgesia had been given with effect. She was aiming to go home and they were awaiting TTOs.

65. As I have noted above, in her witness statement and oral evidence Sister Ursell said that she would not have recorded that the Claimant had had some lunch and not vomited if she was not satisfied that it was correct, and she would not have been discharged if there was any concern that she was not happy to go home or that she was still vomiting. Her invariable practice would be to ask the patient if she had managed to eat any lunch and how much they had managed. As she had written in the records that the Claimant had managed to have some lunch and not vomited then that could only be because that was what she told her when she asked her, otherwise she would not have written it down. She accepted that this information might have been given to her by an orderly, but said that if the Claimant had said that she had only had one spoonful and then vomited she would certainly have recorded that in the records and she would not have been allowed to go home. She was fairly certain that if the Claimant had been sick she would have known about it. There would be absolutely no reason for her to write that she had not vomited unless she was satisfied that it was correct.

66. In the observation chart for 18 February nausea is recorded at 6.19 a.m., though not at 10.25, but recorded at 1415. Vomiting was not recorded in respect of any of those three observation times.

67. The Claimant's clinical observations were all within the accepted normal range on 18 February as were the laboratory values for a patient on the second day after sleeve gastrectomy. It was unusual but not unheard of for someone in her position to require as she did opiate analgesia on the second post-operative day. The experts agreed that her recovery on that day lay within the expected range

with the exception of analgesic requirements and the ability to take fluid orally. They agreed that if she was able to tolerate adequate oral intake it was satisfactory to allow her to go home. They also agreed that if she had some lunch and did not vomit it would be consistent with the description "well". It was reasonable to discharge her as long as there was adequate oral intake.

68. I was impressed by Sister Ursell's evidence. She is clearly an experienced nurse and I find entirely credible her statement that she would not have allowed the Claimant to go home if she had vomited, she would not have written that the Claimant had had some lunch and vomited if she was not satisfied that that was correct. Whether she obtained this information from her own observation or from an orderly seems to me to be essentially by the way. Either way she was satisfied that what she wrote in the notes was the true situation.

69. I consider that, unsurprisingly, the Claimant and her mother may not have had had clear memories of what happened at what time given the number of occasions upon which she vomited and experienced pain and the number of different times on which she had to return to hospital. I intend no criticism of either of them in this regard, but I consider the evidence that the Claimant could not eat lunch without vomiting, which is an essential part of their evidence, is not borne out, in light of the evidence in particular of Sister Ursell.

70. The picture was clearly a developing one. The Claimant in the morning of the 18th was unable to drink fluids without vomiting as noted by both Dr El-Sayed and Dr Oldroyd and Mr McMahon and indeed by Mr Fraser also. The pain levels were raised, as can be seen by the recordings on the 18th of 0 at 1.39 a.m., 2 at 6.19, 2 at 10.25 down to 1 at 1415. The analgesic requirement was raised,

and though unusual that was not such in my view and on the evidence as a whole as to give rise to any significant concern.

71. In the words of Dr Fraser "something had to change". That something was the assessment made by Sister Ursell at 2 o'clock in the afternoon. The Claimant was recorded as having had some lunch and not having vomited and also had oral analgesia with effect. That combination is such in my view as to amount to wellness as subsequently defined by Mr Fraser. It essentially equates to being in a condition where the person is able to go home and cope, and it was in my view perfectly appropriate to decide that discharge could go ahead at that time given that evidence at the time when that decision was made. It was clearly open to the nursing staff to whom the final decision of discharge had been delegated to conclude in light of this evidence that the Claimant had reached a stage of recovery where she could safely be sent home.

72. As a consequence I find no breach of duty in this case.

Causation

73. The pleaded case on causation is that had the Claimant been kept in hospital her fluid intolerance and other symptoms were likely to have persisted or worsened. Imaging of the upper gastric staple line would have been performed on post-operative day two or three. It was accepted in the Particulars of Claim that on the balance of probabilities such imaging would not have revealed signs of emerging staple line leak; however, regardless of the findings of such imaging, it is argued, the Claimant's clinical picture warranted continued admission and

further investigation of the staple line. It is said that early laparoscopy (post-operative days three or four) with or without methylene blue dye testing would have been undertaken and early over-sewing repair along with drainage (post-operative days three or four) would have successfully prevented the full failure of the staple line. It is claimed that the Claimant would have avoided the injuries she suffered.

74. In the joint medical report it was agreed that the majority of leaks are detected several days after the operation, agreeing with the figures quoted in the Kim paper. It was agreed that there are both localised and generalised clinical features of staple line failure. The localised features include epigastric pain and pain on swallowing, difficulty with swallowing and vomiting. Generalised features that may occur somewhat later include pyrexia, tachycardia, tachypnoea, low oxygen saturation and low urine output. It was agreed that there were no features of overt staple line leak on 18 February and that her presentation on that day was not such that laparoscopic or open exploration was indicated. Mr Fiennes was of the opinion that it would have been reasonable not to re-explore on the 19th as long as alternative close monitoring modalities were in place. Professor McMahon considered that the Claimant's condition on the 19th would not have indicated the need for re-exploration.

75. It was agreed between the experts that there is significant variability in the recovery process amongst different patients. If the Claimant was substantially unable to take adequate amounts of food and drink on the second post-operative day and still had high analgesic requirements, her presentation would have been at or close to the limit of the range expected for a normal recovery.

76. It was agreed that the staple line failure was a progressive process that in all probability had begun to develop by 20 February as evidenced by the relatively modest rise in C-reactive protein. It was agreed that on the basis of the clinical history and the level of C-reactive protein on 3 March it was probable that the frank leak developed on 1 March.

77. In light of the report of the radiology expert Dr Tolan, who concluded that a CT scan performed on the 18th or 19th was likely to have shown a small area of fluid in the area around the operation, which would have been judged to be within normal limits for the patient's post-operative status, Mr Fiennes considered that he would have been relatively reassured by negative findings in the context of the patient's overall clinical condition. Professor McMahon considered that he would have been reassured by negative findings given the known clinical condition of the Claimant on 18 and 20 March. It was agreed that if the result of imaging had not provided reassurance, further monitoring and investigation would have been carried out in a manner set out by Kim in the research paper, to which I refer in more detail below. Mr Fiennes was of the opinion that intervention on the 19th offered a reasonable prospect of preventing full staple line failure. Professor McMahon considered it improbable that failure of the staple line would have been prevented by intervention on 19 or 20 February. It was agreed that even if primary repair of the staple line was unsuccessful it was probable that the Claimant would have had a far shorter stay in hospital and that, while a fistula might have developed, it would have been "controlled". It was difficult to know whether or not a stent or stents would have been avoided. It was probable that the pulmonary embolism would have been avoided.

78. The paper by Kim et al is a position statement of the American Society for Metabolic and Bariatric Surgery (ASMBS) on the prevention, detection and treatment of gastrointestinal leak after gastric bypass and sleeve gastrectomy, including the roles of imaging, surgical exploration and non-operative management.

79. A key passage in this paper, which is in effect a summary of current published peer reviewed scientific evidence and expert evidence, is to be found at page 743 (bundle page 202) of the paper. I think it may be helpful to quote the entire paragraph in question:-

> "Tachycardia, fever and abdominal pain (often radiating to the left shoulder or scapula region) are the most common, but not exclusive, signs of a GI (gastrointestinal) leak after SG (sleeve gastrectomy). In general, laboratory examinations are rarely contributory. In patients with clinical signs or symptoms of a suspected leak after SG, UGI contrast studies have a low sensitivity (0% to 25%), though higher specificity (90% to 95%)). Because of its higher sensitivity, most studies recommend obtaining a CT with oral and IV contrasts as the method of choice for diagnosis of a leak in patients who show signs and symptoms suggestive of a leak but remain clinically stable. Inclusion of the chest may help rule out other causes of tachycardia such as pneumonia, pulmonary embolism or pleural effusion. CT results are also influenced by patient factors, the experience of the radiologist, the size of the leak and the contrast material used; however, high sensitivity (83% to 93%) and specificity (75% to 100%) are reported in most series. As with GI leak after GB (gastric bypass) laparoscopic or

> open re-exploration is also an appropriate diagnostic option, regardless of the feasibility of obtaining a post-operative imaging test, when a GI leak is suspected. Re-exploration is characterised by a higher sensitivity, specificity and accuracy than any other post-operative test to assess for leak and should be considered to be the definitive assessment for the possibility of leak when the patient is clinically unstable, or in the scenario wherein alternate diagnoses are being excluded and/or clinical suspicion remains."

80. As noted above, the contrast swallow carried out on 21 February showed no leak, and there is of course the evidence referred to above of Dr Tolan that a scan on the 18th or 19th would not have identified a problem.

81. The experts differ as to the degree of reassurance they would have taken from this. Mr Fiennes would have been relatively reassured and Professor McMahon would have been reassured. I should say that there is no suggestion that the contrast swallow carried out on the 18th or imaging on the 18th would have revealed any different picture from that actually shown by the contrast swallow on the 21st, bearing in mind also Dr Tolan's evidence about what a scan would have revealed on the 18th or 19th.

82. I think it is right to suggest as Ms Mishcon did, that there is something of a change in Mr Fiennes' evidence from what he said in answer to question 13a in the joint statement as to his relative reassurance by negative findings of imaging on the 18th or 19th and what he said in oral evidence that the investigations carried out on the 19th would probably have shown a rise in CRP to between 11 (as recorded on the 18 February) and 52 (as recorded on 20 February) which

would have led to a CT scan being carried out on the 19th and if the Claimant's condition did not improve it would have been reasonable to undertake a laparoscopy on the evening of 19 February.

83. His evidence contrasted with that of Professor McMahon who was adamant that that would not have been a prudent course of action because it would have been important to wait and see how the picture developed. He pointed to the risks to the patient attaching to surgical intervention, although Mr Fiennes made the point that if there were risks of the kind of deterioration that in fact occurred to the Claimant then that type of response was necessary.

84. The position is then that on the 18th if either contrast swallow or imaging had been carried out they would have revealed nothing that would have given rise to concern. I bear in mind the other points of potential concern referred to by Mr Fiennes, in particular the rising of the CRP.

85. My reading of what is said in the Kim report is that as was said in the first part of the paragraph quoted above, most studies (and this includes the Burgos study referred to in evidence) recommend obtaining a CT with oral and IV contrasts as the method of choice for diagnosis of a leak in patients who show signs and symptoms suggestive of a leak but remain clinically stable. It was I think agreed by the experts that the Claimant was clinically stable. It is of course true as the paper goes on to say that laparoscopic or open re-exploration is also an appropriate diagnostic option and that it should be considered to be the definitive assessment for the possibility of leak where the patient is clinically unstable or in the scenario where alternative diagnoses have been excluded and/or clinical suspicion remains.

86. My reading of this is that contrast swallow and/or CT scan on the 18th would normally have been regarded as being sufficient bearing in mind that the Claimant was not clinically unstable even if clinical suspicion remained. I do not read the paper as mandating laparoscopic or open re-exploration in a case where there is clinical suspicion but rather that it is stating that such intervention is the definitive assessment for the possibility of leak. That has I think to be read subject to what was said earlier in the paragraph about the approach recommended in most studies of a CT with oral and IV contrast in the case of a patient who as in this case was clinically stable.

87. I think Mr Coughlan is right to argue that on this point it is not a question of the Bolam test of whether there is a class of practitioners who might reasonably recommend either alternative, since we are concerned at this stage with causation rather than breach of duty. Rather I have to make a choice as between the approaches put forward by Professor McMahon and Mr Fiennes. In light of the evidence as a whole which I have set out above, and bearing in mind the criticisms that were made of Professor McMahon's report by Mr Coughlan, I consider that Professor McMahon's approach is the one to be preferred. There were not such signs in existence on the 18th as to give rise to the kind of concerns which would have justified the surgery which would have been Mr Fiennes' preferred option by the evening of the 19th. It is the case that the changes in the Claimant's laboratory results between 18 and 20 February involved only a relatively modest rise in the CRP and everything else, in particular the WBC, urea and electrolytes and creatinine levels remained well within the normal range. I consider the approach of Professor McMahon of a suspicion of a leak keeping the Claimant in hospital in order to monitor her

progress but not rushing to carry out over-sewing repair without more is the better view in this case. I bear in mind also Mr Fiennes' evidence that the intervention on 19 February offered a reasonable prospect for preventing full line staple failure was that this was 50% likely to succeed and hence not meeting the balance of probabilities test.

88. I conclude that on causation as also on breach of duty this claim must fail.

89. As a consequence of my findings on breach of duty, the claim fails, but, even if I were wrong in that regard, it fails because of a lack of causation.

ANNEX 1

1. In her oral evidence the Claimant adopted her statement as her evidence-in-chief.

2. In cross-examination she agreed that she had not gone to solicitors until 2015 and her witness statement was dated April 2018, five years after the incidents. She agreed also that she had been in and out of hospital several times over a period of several months. She did not accept that the details might have become a bit confused.

3. She was referred to being given morphine after the operation, and it was put to her with reference to the fluid balance chart that she had been given water at 6.00 p.m. and 9.00 p.m. and 11.00 p.m. It was put to her that she had not therefore slept entirely throughout and she said that the witness statement did not state the times. She did not recall having water then.

4. With regard to her reference to vomiting on 17 February she was asked whether this was just retching and gagging or proper vomiting. She said she would not say it was proper vomiting as she had not eaten for a time before and it was just what she had taken in and she had been retching water. She had been given a bowl but she could not reach it and it would have been on her and it was bits of water and it was on a tissue. She had told the nurses on 17 February that she was vomiting. She was referred to the nursing care records concerning the 17th and the reference at 8.30 a.m. to her having occasional sips of water and no reference to vomiting. She said yes, if it was written there, yes. She was referred also to the reference in the nursing care daily care plan at 1800 of her experiencing nausea but not vomiting. She saw that and she said that the note

was wrong and she had been vomiting. It was put to her that also in the nursing care healthcare record when she was seen at 1745 there was no mention of vomiting. She was asked whether she had told the nurses she was vomiting and said again it would have been sips of water if she had been vomiting. She accepted that none of the nursing notes referred to vomiting and one of them said no vomiting. She was saying that the notes were wrong.

5. She had told Mr Menon that she was vomiting. She was asked why he had said she could have clear fluids and a liquid diet the next morning if she had told him that she could not keep anything down. She said he was of the view that it would take a while for her body to get used to it. He had told her this before the surgery. She agreed she had been told there could be difficulties in keeping things down initially.

6. She was asked where the pain was that she experienced on the 17th and she said it was mainly in her back and in the area around her stomach. It had been excruciating pain and she was yelling at that point.

7. It was put to her that the pain scores in the observation chart for the 17th recorded scores of 0, 2, 1, 1 and 1 during that day. She was asked whether she agreed that these did not seem to describe such pain as she was now saying she had and she said she thought the later ones were when she was asleep. She questioned whether these recordings corresponded to when she had taken medication. She was asked whether she was saying that despite the medication she was screaming all the time and she said yes.

8. She was referred to the fluid balance chart of the 17th and the note there of a total of 350 mls of water she was recorded as having had. She was asked

whether she accepted there was no record of her being unable to keep it down. She said no she did not, she had not been able to keep it down, that was one of her concerns when she was discharged.

9. She was asked whether the record for the last two entries in the observation chart concerning nausea and vomiting on the 17th were wrong. They both recorded no nausea and no vomiting at 6.00 p.m. and 2152 p.m. She was asked whether the record was wrong. She said she agreed with that.

10. With regard to 18 February she said she could not gulp anything. It was put to her that it was known that she had drunk one-and-a-half cups of water the previous night and she said yes, over five-and-a-half hours. Everything she needed to have orally she was retching back up.

11. It was put to her that the records showed that she had taken oral medication throughout the 18th and she was asked whether she was saying she could not keep it down. She said yes. She was later given everything intravenously as she could not keep it down. It was put to her that this was a reference to the 18th and she was not given anything intravenously then and she said she could not recall that.

12. She was asked whether she was saying that with regard to the tablets and liquid morphine she could not keep any of it down and she said she could not recall that. It was put to her that if she had not been able to keep it down it would be important to tell the nurses and she said it was reflected by the fact that she was constantly in pain.

13. She agreed that there was no note that she was vomiting on 18 February, especially not oral medication. She agreed that no history of vomiting was recorded in the last four entries in the observation chart, but said that throughout her stay in hospital when she felt nauseous she vomited. It was therefore wrong to record her as not vomiting on the 18th.

14. She agreed that she was aware that on the care plan she was not meant to have anything other than water and clear fluids before. She was asked where she had vomited and she said she remembered she had a yellow Mr Grumpy T-shirt on and remembered the vomit coming down the side a little. The nurses had been aware. There was concern when she went home that she had not eaten anything.

15. She was referred to Sister Moore's note in the planned nursing care record and agreed that if she had been in pain and given painkillers with effect she must have kept them down. She could not say why it was recorded that she had had lunch and not vomited. From after she had the operation to when she went home on the 18th she had not been able to eat anything.

16. It was put to her that she had had lunch and did not vomit it and, with reference to paragraph 19 in her statement, on 19 February she had vomited yoghurt at home and that that was what she must have confused with the previous day and she denied that. She said the reason that they bought yoghurt was she had been told to try it first to see if she could keep it down.

17. With regard to the GP record of 20 March, she agreed that there was no mention of her not being able to eat or drink. It was put to her that if that was her

concern did she not think she would have told the GP that and she said she had done and did not know why it was not there.

18. She was referred to her statement at paragraph 22 where she said when she went back to the hospital on the 20th that she had not drunk anything since the surgery. It was put to her that this contrasted with the notes on the 20th which referred to her being able to swallow liquids, was suffering pain and was apprehensive about drinking/swallowing. In addition there was reference on the 21st to her being able to swallow fluids with no vomiting. She was asked whether she said these notes were wrong as well as she had said she had drunk nothing since the surgery. She said she thought these referred to when she was made to drink a fluid in order to have a scan. It was put to her that that had taken place on the 21st and it was suggested she was able to drink and had been and it had hurt when swallowing. She said she had no comment to that. It was suggested to her that quite understandably she had been confused between what she had experienced when first in hospital and the later admissions when she was much more unwell where there were records of vomiting. She said that she disagreed with that.

19. On re-examination she was asked whether she accepted the truth of what was recorded on the 20th and she said she had not wanted to swallow liquids as it was painful. She recalled being in pain and being dehydrated. She could not remember describing the pain to the GP as chest pain.

20. She had not seen Sister Moore's note when she was an in-patient. She had only seen it in the course of this case. She was literally not able to take a spoonful of yoghurt and could not tolerate anything. She could not swallow or keep

anything down and it was a very small quantity. She said in regard to the observation chart she agreed that it seemed to say she had not had nausea or vomited. She was asked why Buccastem was added on the 17th and she said she thought it was about the sickness, to keep down. She agreed that if the chart was reliable about nausea she had first complained about it at 6.19 a.m. on the 18th and could not explain the disparity and lack of a tick for nausea and daily care plan for the 17th. They were not her documents. She was referred to the clinical records for 18 February where two out of three of the doctors recorded vomiting and was asked if she could say why there was a difference between what the doctors and the nurses had written. She said the nurses had not given a true reflection of what was happening.

21. With regard to the pain scores, she had not been asked to score her pain. They had come on the 17th and she had not been in a position to give her views. She had no memory of any conversation with Sister Moore about lunch on the 18th. She had a memory of there not being a conversation.

ANNEX 2

1. In her oral evidence Mrs Kalair adopted her witness statement as her evidence-in-chief.

2. In cross-examination she said she was aware that most of the stomach would be removed but not as much as to leave only about 20% of its former size. She was aware that the Claimant would need a liquid or fairly liquid diet.

3. On the 17th the Claimant, she said, was unable to eat or drink. She was asked whether she had been aware that she was not meant to be eating and she said yes, but she had just had a sip of water and could not have a sip of water. She had vomited on a number of occasions on the day after the operation. She had seen her vomiting. They had tried to give her a sip of water but she had a bad pain in her back and could not keep it down. She had tried to sip water. She had just had very little sips. She had not kept it down all the time. She had been in bad pain after the operation and could not keep it in.

4. She referred to being told on the 17th to give her ice-cream and watering it down but no food or anything. She had stayed with the Claimant throughout the day and overnight for most of the time but then agreed she had not stayed overnight. When asked why she had said she had stayed overnight she said that was most of the time and the Claimant had bad pain that day and they had stayed with her.

5. She was asked whether the time when the Claimant was screaming in pain had been at that earlier stage or later on and she said she had stayed with her after that in the daytime but not night-time. She was sure the screaming was then and not later. She had told the nurses and they said it was normal.

6. With regard to the 18th she accepted that the Claimant was still able to drink sips but she had pain in her back with it. She could not remember seeing what the Claimant was given for lunch that day. They had only given ice-cream and were told to make it a bit watery. The Claimant had had bad back pain with every sip. She agreed she had not mentioned yoghurt for lunch and the Claimant vomiting on the 18th but she said she remembered it.

7. After the Claimant's discharge she had ensured that she was given her tablets throughout the day and she said she had made it watery to go with them, tried to give her paracetamol but she had vomited again. It was put to her that that was not what she had said in the statement. Half the time she was sick after eating only a little bit of food. She said it was only a little amount and she was not vomiting all the time but was in pain all the time. She had been taking her medication but was not keeping it down the whole time.

8. She was asked whether she recalled what food the Claimant had been given and said it was blended vegetables boiled and mixed and not solid. Her sister-in-law had helped her.

9. She was referred to the history sheet for 5 March and to the Claimant trying to eat mash potato and vomiting. She was asked whether this was what she was trying to give her three days after the operation and said no, it was not three days after. She was asked whether she was talking about the day after discharge and said that she had tried hard to make it watery and it was not solids and they had tried and she could not have any.

10. She was asked whether, given that she had made her statement more than five years after the event, she accepted her memory might not be completely

accurate. She said her sister-in-law had come as well. It was put to her that it was very difficult now to try and recall what happened every day and she could have mixed things up, and she said she remembered every single day what had happened with the Claimant.

11. On re-examination she was referred to Mr Menon's note of 5 March to the Claimant vomiting and being unable to hold down liquids and Dr Robins' note of vomiting being an issue since the day of the operation and she said yes and the Claimant had bad back pain then also.

ANNEX 3

1. In his oral evidence Mr Menon adopted his witness statement as his evidence-in-chief subject to the corrections to the name of Dr Oldroyd and the fact that contrary to what was recorded at his paragraph 16, Dr El-Sayed was FY2 and Dr Oldroyd FY1. This was a reference to the foundation years they were in, 1 or 2, where they had five years on the graduate programme and two years in clinical practice.

2. On cross-examination, with regard to the first admission, he said that almost certainly he would have reviewed the Claimant on the evening of the 16th. She had stayed on the immediate recovery area until 5.00 p.m. after the operation, awaiting an appropriate bed. That was where they housed the patients post-operation and that was his normal practice in order to review the patients post-operation going around the nurses and having a quick word with them. They did not formally document this unless something was going wrong. If there were concerns it was likely he would have looked to check that all was well.

3. He had seen the Claimant at 1745 on the 17th. He had put her on free fluids and trial without catheter. He was asked whether he was surprised there was no record of a note of a post-clinical record from him and he said that the 17th had been a Sunday and he had been operating all day and he had seen the Claimant. Normally he would have written something down and he was surprised to find he had not. They went up at least twice to check the bed was ready for the next patient. It was correct that as there was no note it was not known whether he had examined her. As regards the decision to stop the IVI he said that going by the nursing records and standard practice that it was on the next day. They took

down the IV fluids, the catheter came out. This being the ward round on the enhanced care unit he was surprised there was no evidence in the notes. It was a protocol driven upscaling and unless there were concerns, patients would start drinking and the IV would come down as well. It would be led by the nurses.

4. He was asked whether it was a clinical judgment whether oral intake was good enough to take the patient off the drip and he said yes that was under the protocol. Unless there were problems the patient would start drinking on the first post-operation day and if there was a problem a clinician would amend the protocol. It was put to him that he had not said he had issued the instruction but had said yes to stopping the drip. He said there was no evidence on the notes and he had not given any instruction to the contrary having seen the patient so he must have been happy.

5. With regard to the reference in the notes to 1745 he said that it could be between 8 o'clock in the morning and 1745. He agreed that he said at his paragraph 15 that it was in the afternoon when he reviewed the Claimant. He said it could be in the afternoon and certainly before 1745. The nurses might wait for the surgeon to authorise free fluids and the liquid diet and the trial without catheter. He agreed it would be the afternoon. The timing of the ward round was variable as it depended on the busyness of the surgeon.

6. He agreed that she was seen by the junior doctors at 10.30 on the 18th and the consultants one or two hours later. The junior doctors belonged to the original firm. It was unlikely that the ward round would have been as early as 6.00 a.m. He agreed that the IVI finished at 6.00 a.m. and it was not known at whose direction.

7. He was referred to the reference in the fluid balance chart with the Claimant having sips every couple of hours while the infusion was going on and no intake early on the 17th. It was put to him that if it was a balance this did not really fit that picture and he said nothing was documented and he would expect more information on the chart with regard to oral intake between the time when it was last documented and 1800 hours.

8. It was put to him that it was information that there was no oral intake between those hours and he said that was one way to see it. Ideally steps should be recorded. He agreed that the decision to stop the drip did not seem to have been authorised by a clinician. As regards the decision to remove the catheter it could be a clinical or a nursing decision. It could be for medication or for nursing reasons. He agreed that the nursing records concerning the removal of a catheter suggested it was his clinical decision.

9. It was put to him that as recorded in the nursing care notes if the catheter was removed at midday did he think he had seen her before midday and he said it was a clear note and he had advised on trial without catheter so if one saw the two together he would have seen her before noon. He was asked whether he could be mistaken about seeing her in the afternoon and said he did not have a written clear record and would have seen her at 11.59 or shortly thereafter.

10. He was asked who had prescribed the Buccastem and said that he knew the anaesthetist and it was his handwriting and it was prescribed on the 16th and given on the 17th at 3.00 p.m. It was not known who had given it, he did not know the initials. It could be a medical or a nursing decision but possibly a nursing decision, to be expected.

11. He agreed that there was no clinical record from the 17th and nothing around 3.00 p.m. from the nursing records. She had been given medication to help with nausea and possibly vomiting and this was an antiemetic. Ondansetron referred to at page 167 was similar, it was for anti-sickness and was an antiemetic. He agreed that if someone thought Buccastem was to be given there had to be a clinical need for it. He agreed there was nothing in the nursing or clinical records for 17 February to say that. He was referred to the Buccastem prescription and that for 48 hours she had up to six doses in case of need and her nursing daily care plan suggested she would experience nausea at 6.00 p.m. on the 17th and put together it seemed likely she experienced nausea in the afternoon yet at page 152 she was marked in the observational chart as not experiencing nausea. He said that between the 16th and the 18th there was a total of fourteen observations and two sets of nausea on the 18th. He agreed that there was a plain inconsistency as to what was recorded. The observation chart was what they referred to as a trend. It was noted in the nursing care record as an observation. There were observations by a number of shifts to be seen in the healthcare record at page 151, and the observation chart was a more representative trend.

12. He agreed that if she was experiencing nausea as she said on the 17th and the nursing care record indicated nausea, then the Buccastem should be on the observation chart. Mr Menon noted that there were two observations in the nursing care record and he was being asked about Buccastem at 3 o'clock. He agreed that nausea was not recorded. He agreed that it was known that she had been given an antiemetic and the box was ticked. It had not been filled in as to

which drug and although it was known it was given he agreed that it should be there.

13. Going back to the question of when he had seen the Claimant on the 17th he said he had to go via what was recorded and the catheter was removed on his instruction at noon so he had to have seen her before that.

14. He could not account for the fact that he and Mr Fraser had made the same mistake with regard to the level of experience of Dr El-Sayed and Dr Oldroyd.

15. He agreed that Diclofenac was prescribed at 8 o'clock in the morning and Ondansetron at 2.00 p.m. She was given 15 mgs of morphine at 10.40 a.m. on the 18th. He could not say from the clinical records which doctor had given her morphine. He agreed that there was no reference in the clinical notes for that date to morphine but only paracetamol.

16. Mr Menon said that two junior doctors could take one of three steps. They could stop and put a nil by mouth requirement or continue the status quo on fluids and they would look at the symptoms and see if there was any risk of wound pain. 25 mls was a very small amount, being the equivalent of a single measure of spirits. He would expect them to record it if they were giving morphine but it was not an unreasonable progress report for that level of doctor.

17. He agreed that neither Dr McCullough or Mr Fraser had mentioned morphine. He agreed that given the time recorded in the chart for her being given morphine at 10.40 it was unlikely to be either of them. It was put to him that it was likely that it was the junior doctors or someone else who authorised the morphine and he said he could only guess if it was prescribed by the

anaesthetist and was within the prescribed dose and it fitted in because it was ahead of Dr McCullough and Mr Fraser so it was possibly the junior doctors. He agreed that as with the Buccastem there must have been a clinical indication to give her morphine. The anaesthetist's prescription was within his limits. It could be read as two to three hourly or per day. He agreed that the morphine she was given on the morning of the 18th was the largest dose she had received and was at the limit of the prescription for a single dose.

18. It was put to him that that meant she was in considerable pain. He said that there was a gap between the previous 2 mgs on the 17th six hours before and more than about 22 hours and that could explain why she was given a larger dose now and it was not unreasonable for a single level. He agreed that it could mean she was still in significant pain. It was necessary to look at the pain chart.

19. It seemed that it was Dr Oldroyd who had given the codeine at midday on the 17th. He was asked whether there was anything on the record to say why codeine was prescribed and he said he could not find any reference there and the management of pain was a mixture between art and science and it was fine as long as it was within reasonable prescription limits.

20. He was referred to the fact that he had said earlier there was a trend on analgesia and she had been on paracetamol throughout and morphine every twelve hours or so after the operation and he agreed that there was no other prescribed pain relief given, although it had been prescribed.

21. It was put to him that having the morphine and two new drugs on the 18th which had not been prescribed indicated increasing pain and he said that the morphine was at 15 mls rather than 2 x 10 mls and the total was therefore less and it was

unclear what this was for and it could be for muscular pain as well as abdomen pain and it could be in respect of her back.

22. He was referred to the pain scores for the 18th, the levels of 0, 2, 2 and 1 which indicated in the morning a worsened pain position than overnight and he said yes, there were two 2s on the 18th in comparison to the 17th. He said that they did not have accurate information about the type of pain and whether it was her abdomen or her back.

23. He was referred to the oxygen saturation levels. He said this was the percentage level of oxygen in the blood which could not go above 100. If the person had lung problems after an operation and a higher BMI there were several other reasons why it could go down and she had had some assistance from humidified oxygen to prevent dryness of her mouth and throat. Thereafter she had gone to air and he agreed there was a slight dip, but it was within the caveats mentioned. Level 95 or 94 readings on air was very reasonable. A number of people in the courtroom would be at 95 or 94 level. It was therefore a small point-change for oxygen saturation levels. With regard to pain and nausea, there were the two mentions of nausea at 6.19 and 1425.

24. It was put to him that the reference to nausea at 1415 could only mean she was complaining of showing nausea at around 2.15 and he agreed. He agreed it was after the note at 2.00 p.m. He thought that was the last record there was of a complaint of nausea.

25. With regard to the examination of the Claimant referred to at paragraph 16 of his statement he was asked whether the examination would be done while she was sitting in the chair or on the bed. He said it should be lying down and it

was a difficult decision and he had often carried out such examinations on a patient who was in a chair unless there was a cause for concern. He would get the patient to bed if there were warning signs.

26. He agreed that he did not refer in his second sentence of paragraph 16 to the reference by Dr El-Sayed and Dr Oldroyd to the Claimant vomiting but referred to difficulty in keeping down fluids. It was put to him that it was a nuanced difference and he said that, bearing in mind the observation chart there was no evidence of vomiting on the chart.

27. It was put to him that paragraph 16 represented the note and not the observation chart and he seemed to be downplaying the vomiting and he said that she still had difficulty in keeping down fluids.

28. It was put to him that paragraph 17 did not address what was said in Mr McCullough's note to re-establish the IVI and he said that Mr Fraser seemed to have seen the patient soon thereafter. He was asked why he had not referred to what Mr McCullough had planned and said it was not a deliberate omission but he accepted it was incomplete.

29. He was asked why a consultant might decide to mention a need to re-establish IVI and he said Mr McCullough was a senior surgeon or registrar not a consultant then and it would be to reinsert the IVI or administer intravenous drugs.

30. He was asked when Mr Fraser had seen the Claimant and said it was a little after Mr McCullough. He saw the time on the record. They were not supposed to use watches and it was not an error. It could be that there were changes in the

way times had been documented. He was asked how he could say that it was in the afternoon that Mr Fraser saw the Claimant and said he could not answer the point. Mr Fraser's notes followed Mr McCullough's and at the top of the history sheet it said 12 noon, so it followed.

31. He was asked why when he summarised what Mr Fraser's note said he avoided the reference to vomiting and he said it was not a deliberate omission but it was right he had not pointed it out. As to whether there was any evidence the Claimant at the point of discharge was able to keep down water he said that from what he had heard she drank 350 mls over a five hour period. She would have a very small stomach post-operation.

32. Mr Menon agreed that fluid intake was not recorded on the chart for the 18th. There was no reference to water in Sister Moore's note about lunch.

33. With regard to the discharge letter, a good deal of that would be pre-selected. The clinical summary was all free text. He agreed there was nothing on the contemporaneous records about ability to drink small amounts. If a person was devoid of water orally or intravenously there had to be positive findings he would find on a blood test. He was asked whether there was anything to document what he said here and he said that she had had the 350 mls of water. It was not inaccurate. It was put to him that it was superseded by the three records on the 18th saying she was unable to do so and he said that an entry could have been made and this was not inaccurate. It could be misleading to the GP and it should have more specific details. He could not recall anything in the records other than what Sister Moore said as to whether the Claimant was well enough for discharge.

34. On re-examination he was asked whether the Claimant who had had a good deal of analgesics on the 18th would have been able to take it without water and said unless it dissolved in the lining of the mouth. If a nurse had told him on the 17th that she was unable to keep water down he would certainly not have given instructions for free fluids and a liquid diet on the next day.

ANNEX 4

1. In his oral evidence Mr Fraser adopted his statement subject to the correction to which I have referred above about dates and the name of Dr Oldroyd and the FY1/FY2 specification as between him and Dr El-Sayed.

2. On cross-examination he was asked how he came to make the same mistakes in his statement as Mr Menon had and he said he had been retired for some time and he was grateful for the offer of clerical assistance from the hospital legal department and the typo had come from them.

3. He agreed that there was no reference to vomiting at paragraphs 14 and 16 of his statement. Like Mr Menon he said it was not studiously omitted but was a turn of phrase. It was his turn of phrase. He agreed there was no clinical record for the 17th. He had no further information about when the IVI had been discontinued and why there was no other record.

4. With regard to not referring to the vomiting recorded by Dr El-Sayed and Dr Oldroyd in his statement, he said too much was being made of that. There were occasions when consultants passed by and did not make a record. He had had access to the drug charts when he had set out what he said at paragraph 14 of his statement. He agreed there was no reference to the morphine and the codeine in

his statement. He had not read that part of the charts before he had prepared his statement. He had read some of the medicine charts but he did not remember particularly reading them so perhaps not.

5. It was put to him that he had not summarised Mr McCullough's plan and in his statement there was no indication of a plan to put the Claimant back onto intravenous fluids. He agreed that he had not mentioned this. He was asked whether it was not a significant omission and he said that as the admitting doctor there was an element of safety first which would include an IVI and that had been the emergency team on the day. He agreed that this was post-plan surgery and he said he should rephrase that they were junior members of the team being more cautious. Mr McCullough was a Registrar.

6. He agreed that was a fair inference to draw that Mr McCullough had thought the Claimant was not tolerating adequate oral intake. He had seen her around noon. He agreed that he had reversed Mr McCullough's plan for intravenous fluids. He was asked whether he considered his plan to be wrong or had there been a change and he said he guessed he thought that the Claimant was not so ill and there was reasonable potential for her to go home later and encouraged oral fluids to see if that would be sensible.

7. He was asked whether he was then aware of the complaints of nausea as recorded in the observation chart and he said he would imagine so. He imagined he was aware of the fact that she experienced nausea at 6.00 a.m. Likewise he was aware from the pain scores that the pain level worsened on the 18th. Saturation levels were not significant, being at the 95 and 94 level. He was probably aware that she had had morphine at 10.40 and codeine at 12

o'clock. He would generally look at the fluid balance charts and the drug charts.

8. The decision to discontinue IVI was clinically led and an adequate oral intake would take over from the IVI.

9. He agreed that nothing was recorded concerning the 18th on the fluid balance chart and it was quite possible that she drank nothing or it had not been filled in. He was asked why if he saw this chart he had not done something about that and he said he could not remember what the conversations were with the nursing staff, they must have discussed what the Claimant had and had not had and he would have felt that it was practical to encourage her to drink more before going home. She would have to have had fluid intake with her medication.

10. He agreed that he had noted that on the clinical record that she was unable to keep water down without vomiting. It was put to him that whether or not she had medication with water there seemed to be no history she had had which matched the chart which showed nothing fluid going in and he said it was not an adequate account, he agreed.

11. He agreed that something had to change for her to be well before discharge because he had not immediately discharged her.

12. He agreed that he had been criticised for not operationalising what "well" meant. He agreed that it involved tolerating oral intake and being no longer dependent on strong analgesics though analgesia would be required. He agreed that if she required morphia she was not well enough for discharge. He agreed he would expect her to be on to the non-clear fluids. He said it would not be a

lot but an adequate amount. He agreed that a good trend of observations was needed and an expectation that she would still feel nauseous. She would not be "well" if there was a new or worsening complaint of nausea, nor if she were vomiting. It was correct that if her evidence was accepted with regard to vomiting up the yoghurt then it was not the picture he had envisaged for wellness for discharge. There was always an amount of regurgitation. The patient was unfamiliar with what to take and he could not say someone would go home and never bring anything back. There was a long period of adjustment. She would not be "well" if she was not tolerating water and vomited yoghurt. He was asked whether if she kept the first mouthful of yoghurt down that was enough to be well and he said by itself it would not be enough but it needed to be part of the overall picture. She needed to be keeping the fluids down and being reasonably comfortable and in the nurses' assessment at an appropriate behaviour for that stage with that type of surgery. He was content to delegate that assessment to the nurses.

13. On re-examination he said he thought with regard to the fluid chart that it was a case of nobody filling it in rather than the Claimant not having any fluid. Pain and nausea were to be expected in such a case. The oxygen levels of 94 and 95 were still within the normal limits. It was entirely compatible with her having been on oxygen for two days. If he had felt she looked too unwell he would not have suggested discharge. It was standard protocol for that kind of surgery at that time. He had not thought there was anything unusual.

ANNEX 5

1. On cross-examination Sister Ursell said that she had first learned of the case last month. She had done the dayshift on the 18th. She did not recall whether she had entered the values on the observation chart or not. Usually the HCAs would do that. At that time they would have taken the blood pressure though that was not the case now. Usually as regards pain they would ask the patient and it was between 0 to 3 on a scale of 1 being slight, 2 moderate and 3 severe. It was put to her that she could not account for the two yesses referring to nausea and she said she believed in what had been put there. The daily care plan was the domain of the nurse and not the HCA. She had put it all in. With regard to the tick in the nursing care notes for oral morphine she said that was for an oral analgesic that would include paracetamol. She did not know who had given oral morphine as set out in the as required drugs chart. It was not her signature. She would expect it to be a nurse. It was pre-prescribed. It was put to her that there was nothing in the nursing care box for nausea on the 18th and she said she thought they were waiting to see if the nausea had settled from earlier and forgot to fill it in. You would fill it in even if she was discharged before 6.00 p.m. It could be written if there were nausea and/or vomiting at another time. If the nausea has been from earlier they could have forgotten to fill in the nausea box in the nursing care chart after the Claimant was discharged.

2. With regard to what she said at paragraph 11 of her statement that she was fairly certain that if the Claimant had been sick she would have known about it, she said looking back at her records she did not recall any vomiting. She was referred to the clinical records on the 18th with reference by two doctors to

vomiting and said she did not recall vomiting and that was all she could say. She was asked whether she intended to cast doubt on what the Claimant said about this and she said there was no evidence she had documented that the Claimant vomited and she would have thought she would have documented something about it. She had read through the clinical records before making her statement. She was asked why she had not referred to the reference to vomiting and said that she had written in the nursing notes that the Claimant had not vomited and could not recall her doing so.

3. She would have been aware that the Claimant could be returned home if she were well. That was what had been written in the notes. This drug plan had to be written by a junior doctor but if she did not deem the Claimant well then she would not have discharged her. It was put to her that Mr Fraser had not referred to a junior doctor being involved and she was asked whether the burden was on the doctors or the nurses, and she said it was a joint decision. She was asked whether Voltarol was not the only medication given and said no, there was a reference to analgesia there also. She was asked whether by that she meant to encompass the morphine and the codeine and said yes.

4. As regards what she said about "some lunch" she could not recall how much the Claimant had had, but she must have had something. She could not claim recollection of a conversation. She had written that the Claimant had had some lunch. She agreed that her note did not describe a conversation and was consistent with her having been told by someone else. It was put to her that it could have been the HCA clearing lunch away, and she agreed that someone could have said that the Claimant had had yoghurt. It was put to her that

equally the reference to not vomiting was liable to mixed messages and she said that the Claimant had complained of nausea earlier so she would have asked her if she was feeling sick.

5. It was put to her that there was no reference to wellness in her record and she said the indications were that she was all right. She would be experiencing pain and nausea after this surgery.

6. With regard to the assessment about adequate oral intake there was nothing in the fluid balance chart and she assumed that was discontinued before she had come on shift. The night staff tended to put the charts in. The record of the 18th was not in her handwriting. She could not remember whether there was an assessment in the 2 o'clock records of the Claimant's ability to tolerate fluids. There was nothing saying she was drinking fluids.

7. It would have been all right to discharge the Claimant if she had taken a little yoghurt between 1 and 2 if she thought it was settling: that meant if she was feeling settled and comfortable.

8. She was not aware of the Claimant being taken to her car in a wheelchair but said again that would often be requested in such cases. She did not recall the Claimant and her family complaining that she was not well enough to go home. With regard to paragraph 11 of her statement, the Claimant had been sitting out at times.

9. On re-examination Sister Ursell agreed that many patients would have pain and nausea and she had looked after many such patients. They would not have sent

her home if she was displaying unusual signs of pain or ability to take fluids or if she or her family were unhappy about her going home.

ANNEX 6

1. In his oral evidence Mr Fiennes made minor typographical corrections to his report and also the reference to 6.00 a.m. at paragraph 13 should be 6.00 p.m. and likewise at paragraphs 17 and 20.

2. He had not changed his views as a result of any of the previous evidence.

3. He said that for the Claimant to be experiencing adequate oral intake with regard to discontinuing the IVI and her fitness for discharge this involved being able to support normal physiology and keep the body working usually with appropriate amounts of fluid intake and urine levels. 1 litre of fluid would be the bare minimum for a normal adult.

4. With regard to her recovery on 17 February, he said it was within normal limits but there should have been a little caution where a couple of her temperatures were above baseline and the analgesics were falling. CRP and total white blood cell count were normal. The neutrophils were marginally elevated. The pain scores varied but she had morphine twice so that should be seen in that context. It became an issue later on with the onset of nausea. On the 18th she was unable up to lunch to tolerate an adequate fluid intake.

5. It was unhelpful not to have the clinical record for the 17th.

6. On the 18th her condition had not improved in the way he would have hoped for. There was a lack of intake capacity and she had taken further strong analgesia

mid-morning and that was a concern. The CRP was at the quoted limit and the pain complaints would continue and she was vomiting. There was no need to send her home that day. He agreed there was no sign of staple line leak but it was wrong to send her home as she was still experiencing pain and had fluid intolerance. He agreed that profiles varied and the other end of the scale might be a person sitting up watching television after the operation. As to how the CRP worked, it was in the blood and responds to tissue damage and inflammation and it rose linearly and there was an element of speculation and you would expect it to be in-between on the morning of the 19th. It was difficult to say whether the likely inability to tolerate fluids and pain, nausea, vomiting was part of the process linking the CRP to a leak or were separate processes. Pain and fluid intolerance were pointers to staple line failure and the rise in CRP was relevant and there was reference to this in the joint statement.

7. He said that if she had been kept in on the 18th, by the 20th there would have been epigastric pain and that would have become more prominent on the 19th and she would have been able to drink fluids, would have experienced pain and he would have expected significant pain on swallowing. There was no reason to think there would be a decrease in the analgesic requirement. The CRP had risen albeit modestly and there was increased pain on swallowing. This would have concerned him and he would have to consider the risk of harm if it were not dealt with. The findings were compatible with staple line failure and it would need further investigation.

8. If a CT scan were performed or there were confirmatory changes that would support the condition if it did not show abnormal features he would not be

reassured unless it was clear that the clinical picture was improving. Laparoscopic exploration would be the next step. It would involve a CT scan on the 19th and if things had not improved by the evening it would be reasonable to do a laparoscopy in the evening. He thought the die was cast by the time of readmission on the 20th. It went on into the 21st and the chances of preventing the failure which began on the 17th or 18th progressing to a frank leak had probably been lost, certainly by the 21st. The likelihood of success was less and less as the 20th went on. He had experience of successfully altering the outcome after laparoscopic gastric surgery leak.

9. As regards what he had said in the agreed statement that intervention on the 19th offered a reasonable prospect of avoiding failure he said it was 50% likely to succeed. The literature experience was based on a very small number of patients. The later you left it the less likely it was to be successful and if it got to a frank leak it would involve a long and complex illness. It was very difficult to infer anything from the delay. She was clearly unwell when she was readmitted on the 20th. He was asked whether even if a failure had not been avoided whether injury would have been less as said in the joint statement, and he said it was very easy to agree that. Stenting would not have been avoided, it was reasonable to do the other things at that time.

10. On cross-examination Mr Fiennes agreed that a sleeve gastrectomy removed about 80% of the stomach which would therefore be a fraction of its former size afterwards. Also he agreed that the Claimant had been morbidly obese with a BMI of over 55. He also agreed that the patient had to learn to adapt to a significantly limited oral intake and it took time to adapt. That was relevant to

previous portion sizes and there was a learning curve as to how much food a person could manage. There was a perception that such people ate too much and bolted their food but that did not have to be the case. Adaptation was needed after surgery. He agreed that some took longer than others but it was not a question of whether you could manage a small amount such as 25 mls. He agreed that there were huge variations. Some people were nauseous and vomiting in the first few days after surgery but some were not. The question was what inference could safely be drawn from that. Patients needed to learn that it was not the same as not being able to swallow one teaspoon full of yoghurt.

11. He accepted that the diagram attached to his report describing the creation of sleeve gastrectomy might have an inaccuracy in that it showed the gastric sleeve wider than the oesophagus. It was a schematic diagram and not intended to be diagrammatically accurate to show that it was important to have a tight fit between the bougie and the stomach. Early on it would be filled by a single teaspoon. There would be swelling, this was always the case after an operation and it was necessary to account for it where it was not a problem. The question was whether it was in the interests of patient safety reasonable to send them home. He would look at the objective signs, for example pain. He agreed that pain thresholds vary and the question was whether the finding required scrutiny. It was put to him that the Claimant had had to be encouraged to mobilise on the 18th and that would lead to pain and hence an increase in pain and he said that wound pain tended to be minimal by the second day. The fact that she was not mobilising until the 18th did not mean you could deduce it was because of a worsening of the wound pain. It was put to him that she had experienced pain

when she began to mobilise, and he questioned the physiology of that suggestion.

12. He agreed that he was not concerned about the events on the 16th and there was nothing to worry about in the lab results.

13. With regard to what he said at paragraph 13 of his statement about the SaO_2 never falling between 98% and the pain score fluctuating, he agreed that the Claimant had been on oxygen at that time and until the 18th. He agreed it was unsurprising that the oxygen levels remained high. He agreed there was no mention of nausea or vomiting in the nursing care notes and it could be seen from the fluid balance chart that she had taken a total of 60 mls of water between 6 and 11 and was then asleep. He agreed there was no mention of her not being able to keep the fluids down. With regard to the absence of any reference to vomiting in the daily care plan on the 17th, he said there was no reference to the taking of Buccastem at 3.00 p.m. With regard to the absence of any record of vomiting in the nursing care plan, he said it did not say there had been no vomiting, he simply had to tick a box. He was asked whether he was saying the report was wrong and he said it might be wrong about vomiting and there was no dispute about vomiting on the 18th, which was of greater concern.

14. He agreed that, with regard to pain, oral analgesics had been given on the 17th and there was no note to say she could not tolerate it. With regard to the nursing care notes referring to trial without catheter there was nothing said and he said that it was on a chart about oral intake. It was put to him that there was, on the 17th and he said it was in the evening after the note and it was 350 mls

from 1800 hours. It was put to him that it said she had passed urine, he said he assumed that she had been adequately hydrated in the recovery room.

15. He was referred to the absence of references in the observation chart on the 17th to nausea and vomiting and he said that nausea was noted in the care plan. It was put to him that these were by different people and they were snapshots. She had had nausea before 6 o'clock and had antiemetics and he said there was an issue of reliability as it was not recorded.

16. With regard to what was said at paragraph 26 of his report he agreed that blood pressure, temperature and respiratory rate were normal. There were three successive readings where it was rising. The SaO_2 was the lowest it had ever been. He agreed that this was the first reading after she had been taken off oxygen and was still within normal limits. It was put to him that therefore there was nothing particularly untoward and he said nothing on its own was untoward but you had to look at the overall picture.

17. It was put to him that the nursing care notes contained no mention that the Claimant could not keep painkillers down though it would have been of concern if she had brought up the medication and in fact all the medication on the 18th was oral except for the suppository and there was nothing to say that it came back. He agreed. He said the morphine prescription could have been oral or not.

18. As regards the signatures on the drug chart this was outside his knowledge as to whether if there were two signatures this meant it had been given intravenously and only one signature if it was oral.

19. He agreed that for the 18th there were two entries on the observation chart for nausea but not for vomiting. The reference to very mild wound pain by the two junior doctors on the 18th was not unexpected after surgery. It was put to him that if she was not keeping fluids down and urine was being passed easily that would not have happened and he said that if she had been properly hydrated she would carry on passing urine for a while. As to whether he accepted their impression that she was well he said that they had written "well" and they were two very junior doctors. He agreed that Mr McMahon noted that she was stable and had good urine output as well as saying that she was unable to tolerate water.

20. It was put to him that there was no reference to pain, and he said this was 90 minutes after she had had 50 mls of morphine.

21. He agreed that there was no reference of pain to Mr McCullough. It was put to him that there was no reference to pain in Mr Fraser's note and he said that that was notwithstanding the pain scores on the chart. He agreed that it was level 1 by 1.00 p.m. As to whether he accepted what they had written was what the Claimant had told them, he said he accepted there were three records by different doctors saying that she could not keep down fluids and they did not say what the source of the information was. It was put to him that the history always came from the patient and that was the practice. He was asked whether he accepted that the three doctors before Mr Fraser had described her as well and stable although they had been told that she could not tolerate water and he said that was what they had written down. He agreed that in the joint statement the experts had agreed that it was within the normal range. It was put to him

that all the objective evidence was that it was fairly normal for such patients and he said no that it was an unusual analgesic need. He agreed that the clinical observations and lab values were normal for such patients.

22. He agreed that issues of fact were for the court. It was put to him that paragraphs 38 to 41 of his statement were in effect taken on the basis of the Claimant's version of events and he said not completely and there was doubt about what she would tolerate and hence doubt about whether to send her home. He accepted that what she said about yoghurt was a matter for the judge. He stood by what was agreed in the joint statement that if she had had some lunch and did not vomit that would be consistent with the description "well".

23. He was asked whether if there was no need to send her home it could be reasonable and he said yes and only half of patients went home by the end of day two on the statistics and that was the context of there being no need to send her home.

24. He was referred to the clinical indicators listed in Annex 2 to his report. It was put to him that there was no unexpected pain in this case and he said that they had agreed there was an unusual level of pain relief. It was put to him that he had agreed that people had different pain thresholds and that on the day of discharge the only pain she experienced was very mild and she said she had been given 15 mgs of morphine and also rectal Diclophia. He agreed that she had not had a raised heart rate. He accepted that the individual pointers did not reach a level of significant suspicion. As regards loss of function she had had difficulty in swallowing. As regards falling urine output he said it was not measured and it was put to him there were two notes of good output and he said

yes. There was a loss of function with regard to transport of water down the sleeve tube.

25. With regard to the lab indicators the white blood cell count was normal and the CRP was normal and the urea and electrolytes were normal. It was put to him that that meant she was taking adequate fluids and he said no it would take some time to affect her. She had had IV fluids until the previous morning.

26. With regard to what he said about vigilance and monitoring in the Kim paper he said he still thought the leak should have been suspected on the second post-operation day. He said it was necessary to read on and there were relevant concerns, and it was talking about leaks not evidence of staple line failure. He agreed that the leaks were diagnosed many days later. As to whether he still thought the leaks should have been suspected on the second post-operation day he said that the progress of the staple line failure should have been thought about and there was a suspicion and a reason not to send her home. It was put to him that none of the matters referred to at page 202 of the Kim report had occurred on the 18th and he said the Claimant did not have a leak and these were signs of a leak.

27. The process had begun. With regard to the Burgos and Jurowich papers, the joint statement addressed the clinical indicators. It was said in answer to question 7h in the joint statement following on from the answer to question 7b. He was referred to what was said in the joint statement in answer to question 8b that if the Claimant was substantially unable to take adequate amounts of food and drink on the second post-operative day and still had high analgesic requirements her presentation would have been at or close to the limit of the

range expected for a normal recovery. It was put to him that being in the range expected it was reasonable to allow her home. He said that being at or close to the limits suggested that it would be prudent not to let her go home. Decisions were not made about small margins but one looked at the overall clinical picture and she was displaying those features. It was a matter for the court. With such a patient a prudent doctor would ask what might lie behind things.

28. With regard to causation he agreed that even if she could not keep a mouthful of yoghurt down on the 18th and her condition otherwise was at the upper end of normal limits there was nothing to show a need for imaging on the 18th. He agreed that if she had been kept in she would have been monitored carefully. He agreed that as he had said you could infer her presentation on the 19th from her progression between the 18th and the 20th that her CRP would have been between 11 and 52 but between the 18th and the 20th she was able to swallow liquids but it hurt her in the upper gastric region. It was put to him that if one took that for the 19th it would not have caused any particular concern and he said the rise in the CRP would be surprising. It was put to him that he said in the report there was always a delay in CRP rise post-operation and that was several days and he said he thought that he said several hours. He agreed that it was probably not compatible with the claim on readmission on the 20th that she had epigastric pain and could swallow but was apprehensive and her urea and electrolytes were within normal limits. She had drunk nothing since surgery on the 16th. It was put to him that the CRP being at 52 with reference to the answer to question 11a in the joint statement was a relatively modest rise and he said it was a rise. As to whether it was consistent with recent surgery he said it was the fourth day and it was usually falling by the fourth day. It was put to him

that it was a very modest rise and not a cause for alarm and he said that overall consideration was needed. It was put to him that there was nothing particularly untoward in the clinical presentation or the lab results on the 20th and he queried that in relation to pain on swallowing. It was put to him that although the epigastric pain on swallowing required monitoring it could not be described as particularly severe and he said there was no description about severity either way. It was put to him that given her clinical presentation and lab results it was unlikely imaging would have been carried out by the 20th and he said it would have done on the 19th. This was an issue in the joint statement on which they differed.

29. It was put to him that the contrast swallow on the 21st did not show the leak and he said it probably did not stand to be able to detect a median point and could not be identified before there was a hole. He agreed that in line with the radiologist's evidence a CT scan on the 18th or 19th would not have shown a leak. In answer to question 13a in the joint statement he was referred to where he said that he would have been relatively reassured by negative findings of imaging on post-operative day two or three in the context of the Claimant's overall clinical condition. He said yes it depended on the clinical condition. He was referred to what had been said earlier about that that she had some problems with pain on swallowing but could drink. Her blood results etc had been considered. He referred to the CT scan and what was said in answer to question 7c. He agreed that the poor transit of contrast during a contrast swallow or narrowing of the sleeve might be of significance depending on the clinical context. He agreed he would have been reassured by it if the patient were progressing. If the x-ray report did not answer the question completely a

laparoscopy would be logical as there were high stakes and a missed leak was a threat to life.

30. He agreed that the Claimant's position was that she complained of pain in the epigastric region when swallowing and had no problems with her stomach and on 21 February she was able to swallow fluids and it was the case that she was well other than pain causing her a reduced oral intake. He agreed that even if a scan had been carried out that would not be a cause for urgent surgery but he would keep an eye on her and see if she showed improvement. It was put to him that on the 20th the lab investigations were absolutely normal and he pointed out the rise in CRP. It was put to him that on his evidence it was reasonable that there was no surgery on the 19th. He said that if there was awareness of the window for dealing with the matter successfully was closing then there was limited time.

31. He agreed that he had said in examination-in-chief that if a scan had been carried out on the 19th and she had not improved by the evening it would have been reasonable to do a laparoscopy. It was also the case that the later it was left the less likely it was to be successful. It was put to him that the scan was done and nothing remarkable was seen such as to do an operation on the 20th and he said there was a rise in CRP and pain on swallowing. It was put to him that that was a very modest rise. He agreed that he had accepted earlier it was less likely to be successful the later on on the 19th the laparoscopy was carried.

32. As regards his answer to question 14a where he had said that the intervention on the 19th offered a reasonable prospect of preventing full staple line failure, it was put to him that that did not amount to the balance of probabilities and he

accepted it was a vague statement. The figures were in respect of very small numbers of patients. With reference to the Kim paper, there was, he agreed, a proximal leak, and he agreed that the papers said that they were in the setting of very early reoperation (48 to 72 hours post-operative) primary suture and repair of the defect had been described as effective but its efficacy decreased significantly thereafter and in the setting of a distal leak, primary repair including suture or restapling might be more effective than in proximal leaks.

33. He was referred to the Burgos paper which showed on day two you could deal with it and on day three it failed and the Jurowich paper at page 209 where if all had to have stents, all had full leaks and he said yes and it was their preferred treatment. When you did the gastrectomy and put up a staple line if one over-sewed that line the question was whether it was effective in preventing leaks and there should have been a suture repair in this case. In the Jurowich paper there was a four year period and a leak rate of 10% and that was high though it showed if there were small numbers cautious inferences were to be drawn.

34. He agreed that an over-sewing repair would have been unlikely to succeed on the 20th. It was put to him that if there had been repair surgery on the 19th or 20th it was unlikely to be successful and would have required stents in any event and he said that 50% of a sample of two people was not reliable. In the case he had dealt with he was probably lucky to get closure on the third day.

35. He agreed with what was said in the joint statement in answer to question 6b that the claimant's pre-operative risk profile showed a moderately increased risk of death. He accepted that she was a relatively high risk patient. He was asked whether he accepted that other than epigastric pain on swallowing otherwise

there were no clinical signs or symptoms said to be typical of a gastric sleeve leak and he said there was the rise in CRP and the period of intolerance of oral fluids. He accepted that on the 20th all the blood results were normal except for the modest CRP rise.

36. It was put to him that in those circumstances given that the Claimant was morbidly obese, had a BMI of more than 55 and the other factors noted in response to question 6b no-one would have subjected her to surgery or general anaesthetic unless it was urgent. Mr Fiennes took the opposite view and said the case was stronger and the high risk patients were the ones who would do badly if the leak was missed. It was put to him that the higher at risk they were the more you had to be pretty certain and he said you did have to be certain enough and pointed out that in the joint statement it was said that anaesthetic risks would not change the view. He did not think it was reasonable not to subject her to further surgery on the 19th or 20th for the reasons he had given.

37. On re-examination Mr Fiennes confirmed that he had said in his statement that rising CRP typically trailed behind the events with a few hours delay. He said it would be the 19th or possibly 18th and with regard to Professor McMahon's figure of 36 hours he said there was a range and that would push it back to the 18th.

38. With regard to her pain score set out in the observation chart, there was a level 3 after the operation, and fairly quiescent on the 17th and scores of 2, 2 and 1 were recorded on the morning of her discharge. He was asked whether he would anticipate mild wound pain to be level 2. He said he would not and he said it need not be located to the body surface.

39. He understood that factual issues were for the court. If the court accepted the Claimant had had yoghurt and did not vomit he did not agree that that would be adequate oral intake for discharge. It would still be necessary to deal with the question of the ability to drink enough at home to keep her body function normal. Consuming a whole pot of yoghurt would be a parsimonious interpretation of "lunch".

40. He remained critical of Mr Fraser's failure to operationalise the meaning of the word "well". He did not embrace the totality of wellness. Consistency was not coterminous but was a component. He agreed with Mr Fraser about adequate oral intake and non-reliance on analgesics.

41. With regard to his answer to question 8b the presentation being at or close to the limit of the range expected for a normal recovery, he was asked whether he was answering a discharge question or a normal recovery question and said he understood he was being asked about the process of recovery presentation. It could not be reasonable to discharge a patient at one extreme of normal recovery for day two.

42. With regard to the 19th, assuming reasonable care had been in place had there been some improvement it would have been reasonable not to re-explore on the 19th. He was asked whether it was likely from what we knew that there would have been improvement and he said not from her presentation on the 20th. If there were no improvement then it would be necessary to carry out imaging and thereafter she could have needed a laparoscopy.

43. With regard to the answer in the joint statement to question 10a if the Claimant were able to tolerate oral intake there was no material cause to suspect the

potential staple line leak but if she was unable to tolerate oral intake that possibility had to be considered, he said yes it had to be considered before discharge if the court found she was unable to tolerate. The answer to questions 7h was a logical continuation from the answer to question 7b.

44. With regard to the Kim paper, he was asked whether the Claimant was clinically unstable on the 18th, 19th or 20th and said she was not clinically unstable on the 18th. He was asked whether this was a case where alternative diagnoses were excluded and he said it was a case of clinical suspicion remaining. What was said in answer to the second paragraph of question 7c of the joint statement that if there was continued suspicion of leakage, despite negative imaging, relaparoscopy was the most reliable diagnostic aid, was from Kim's and his own experience.

45. He was asked whether with regard to the answers to questions 14a and b in the joint statement whether anyone would be able to say whether a stent could be avoided and he said once a fistula had developed there could be cases where stenting was avoided but it would be needed. As to whether the literature assisted, he said there was assistance from the Kim paper but any one paper might be flawed.

46. As to whether what he said in answer to question 14a in the joint statement about the reasonable prospect of intervention on the 19th of presenting full staple line failure, whether it was an even chance and his opinion had changed, he said that on the 19th and 20th she was in a zone where the prospect of a successful outcome changed and it was a sliding scale of likelihood of success.

ANNEX 7

1. With permission Professor McMahon put in three diagrams. Mr Coughlan had some concerns that they should have been prepared earlier and questioned their value but upon consideration concluded that he was happy for the three documents to be part of the evidence. He retained reservations however.

2. Professor McMahon provided some details as to what the three diagrams represented. In essence they were designed to show how a sleeve gastrectomy worked.

3. He considered it was very tough on patients to have such an operation as it involved a fundamental change in a lifestyle aspect as regards both volume of food and how much to take and how much to bite and it was a tough struggle.

4. The back pain experienced by the Claimant was not very uncommon, particularly with patients with high levels of BMI. There was musculoskeletal pain after surgery. She had had two hours surgery and that could be the most painful experience after the operation. It would not lead you to suspect a staple line leak. It was usually clear that it was of musculoskeletal origin.

5. He was asked whether mobilising impacted on pain and said if you had, for example, a painful joint mobilising could be very painful. If a person had been immobile for a day or two then it could be uncomfortable to get up and start moving.

6. He was asked whether the Claimant's level of analgesics on the 18th was unusual given that it was the first day of mobilising and he said it was still unusual on the second post-operation date to need opiate analgesics and 90% of

people would not but it was not particularly unusual. It would not be considered very much out of the ordinary. You would take note of it.

7. He was asked whether there was anything of concern in the lab results on the 18th and he said the only unusual thing was that the CRP was not higher, but that would not cause alarm bells to ring.

8. He was asked whether he had any comment in respect of what was said at Mr Fiennes' report at paragraph 33 as to whether water in comparison with soup or yoghurt was appropriate. He said that most surgeons and nurses were aware that some patients found cold water difficult and then soup or tea or yoghurt might be more acceptable. Whether she could keep it down was one way of putting it.

9. He would call the 18th the second post-operation day and that was a normal day to intend to discharge a person after such surgery. The issue was dependent on whether her oral intake was adequate prior to discharge. He had heard no evidence other than that from the Claimant that there was any inadequacy of oral intake before discharge.

10. He agreed that one spoonful of yoghurt would not be adequate intake but there was no evidence other than what the Claimant said as to what she had had for lunch and how much.

11. With regard to causation, however the Claimant would have progressed if she had been kept in on the 18th, he agreed with Mr Fiennes that the CRP reading would be between the 11 of the 18th and the 56 of the 20th on the 19th. It was put to him that the lab results of the 20th were all normal other than the CRP rise

and he was asked whether it could thus be assumed that it would be the same and he said that that was a more than reasonable assumption. It was difficult to say that imaging would have been done on the 19th. If the CRP had been measured on that day and increased as was expected and if there was increasing evidence of pain on swallowing, then it would be reasonable to investigate mainly with regard to obstruction in the sleeve and there could be a swelling/oedema or a kink in the sleeve preparation. It was reasonable to proceed to the contrast swallow.

12. He was asked why he said that was preferable rather than a scan in contrast to Mr Fiennes' view. He said he thought this was because the contrast swallow was quicker and easier to arrange and probably a more useful investigation if one were considering an obstruction to the flow as being the main problem and it was probably what the majority of surgeons would initially select.

13. The only change in results from the 18th to the 20th was the CRP. He was asked whether most surgeons would operate in the face of a negative or equivocal scan if the CRP was at 56 being the only non-normal sign and a complaint of pain on swallowing. He said it would be extremely unlikely especially if it was not a specialist bariatric unit to consider an operation given the BMI, three days after the operation and the observations all being within the normal range. Likewise with the biochemistry, the only symptoms suggestive of obstruction and possible localised perforation especially with a contrast swallow showing no evidence of a leak from the sleeve or obstruction.

14. As to what should have been done on the 20th, on the assumption that the CRP was at 52 as it was and that symptoms worsened somewhat he thought further

monitoring of the vital signs would have been appropriate. She would have been kept in hospital and further investigations such as a CT scan would have been considered. It would not necessarily have been done as there was no great urgency and would make no real difference to the outcome and one would be reluctant to put her to the risk of a further operation under general anaesthetic unless there was fairly convincing evidence of the need to do so. That could risk harming the integrity of the staple line. So he did not think intervention would have been considered on the 20th but investigation, as was done.

15. He agreed that if one assumed a CT scan would have been done on the 20th that as said by Dr Tolan the radiologist it would have been equivocal. He was asked how suspicious of a leak in the face of that scan and the laboratory results should they have been on the 20th and he said the objective evidence for such a complication on the 20th would be the CRP of 52. All the other evidence was subjective and there was great variety in patients' subjectivity in how they could take food and how they took pain. It would have been rash to risk a general anaesthetic without more evidence of development of a significant complication.

16. When cross-examined by Mr Coughlan, Professor McMahon was asked whether he disagreed with Mr Fiennes who said only half of patients went home by day two. He said he was not sure he had evidence with which to agree or disagree and did not know where the evidence came from concerning the day of discharge. In his experience most of them went home on day two.

17. He was referred to his diagrams and said they were there to illustrate the relationship between the diameters. He was asked why this evidence was only

provided today and he said he prepared it to try and aid his explanation for the events of the case. The issues become clearer. They had had the joint report and considered the mechanics of leakage from the sleeve and it was designed to assist the court to understand what was happening.

18. He was asked whether he agreed with Mr Fiennes that it was a process, i.e. the breakdown of the staple line and said there were two components to it. There was a failure to construct the staple line adequately initially as could be seen at the top of his diagram number 3. He agreed with Mr Fiennes that it was a process that progressed to frank perforation. He agreed with the answer to question 11a recorded in the joint statement. The frank perforation was the event on 1 March. He had no disagreement with Mr Fiennes about the mechanisms. He had no particular objection to anything set out in Mr Fiennes' Annex B. This was information that was generally known. It was put to him that if there had been signs of inflammation and later infection the process had to reach a certain point and he said there were a lot of variations in the nature and speed of the process but yes. There was no real doubt as to the conclusion. There was no alternative course for the elevated CRP and that was what was going on and he and Mr Fiennes agreed.

19. He agreed that if she had been kept in it would have involved a progression to drinking liquids and when she came back on the 20th she had given the impression of dehydration. He agreed that it was thought she was apprehensive because of the pain. He was asked whether he was not saying that her first admission problems were discrete and explained by another cause and he said he agreed the CRP was part of the process. As to the difficulties in drinking he

did not know whether at that time it was due to the strangeness of this new situation or because the process of inflammatory reaction was already in train. He agreed that adaptation could cause problems.

20. He was asked whether he was seriously saying that the events were part of a different clinical nature from that of the 20th. He said that the first post-operative days were difficult with taking water and on the 20th she had pain on drinking so he did not know that it was reasonable to suppose that the difficulty in drinking was due to a complication of the sleeve and different symptoms could have been an evolution from the expected difficulties after this operation and the complication of the sleeve. This was based on the lack of changes in the observations and the biochemistry and the white cell count. There was a modest rise in CRP and it was difficult to relate to the drinking problem in the first two days and there were different symptoms on the 20th. He did not accept it was the same process throughout.

21. It was put to him that Mr Fiennes disagreed with that and he said the first two days symptoms were what you would expect after a sleeve gastrectomy so it was incorrect to attribute them to a pathological process which subsequently evolved. One was gradually evolving into the other and there was a development.

22. Professor McMahon was referred to the structure of his report and it was put to him that unlike Mr Fiennes he had not set out the principles and the post-operative management in the abstract. He said that part 2 was partly intended to do that while putting the chronology into the context of the explanation. He agreed that he had not explained anywhere his understanding that it was a

process. It was put to him that some reading it might think the case was about frank leak and he said he was not sure how to respond. There had been a frank leak eventually.

23. He was referred to page 35 (page 165 in the bundle) of his report where he said no leak would have been revealed so it would not have been on the 19th or 20th and was asked whether he thought her case was concerning frank leak before discharge. He said he was not sure it occurred to him in that way and it was an evolving process.

24. It was put to him that he had not explained when he thought the staple line failure began and what would have happened with reasonable care and he said he thought he had put that.

25. He agreed that the word "potential" had been used with regard to the staple line leak in answer to question 10a of the joint report. He was asked whether he agreed that if she was not drinking enough staple line leak had to be considered and he said you always consider bleeding leakage and stenosis and it could be difficult to know what was the cause of the problem. He was asked whether if the patient could not tolerate oral intake there would be a clinical suspicion of those three and he said yes but it was a question of the extent to which there was believed to be such intolerance. He denied having changed his view because of the raised CRP. It was put to him that originally he had thought on the 20th it was the legacy of the surgery and he said it depended upon whether you took a lateral reading or later on. He did not think he had changed his view on this. He was referred to what he had said at paragraph 158 that it might have been a legacy of her recent surgery. It said no more than it might have been. He was

looking at it in a chronological sense. On the 20th the CRP was at 52 and that could be a result of the surgery, but at the time that would have been a reasonable assumption if it was documented by a subsequent decrease in CRP.

26. He disagreed that no-one had been thinking of the process. The request for the contrast swallow was a reference to leak indications considering it as a reason for readmission. He did not disagree with the point made that this did not involve thinking about an evolving process but said you could employ hindsight and for the clinicians at the time it was quite reasonable to accept the contrast swallow result and continue observation.

27. With regard to breach of duty he was asked whether the witness evidence had not been sent to him and he said he might have omitted to include it and he could not believe he had not had it. He had not reviewed the witness evidence in the report. He thought he had covered the issues in the report and the object of the report was to describe the more objective elements from the clinical records without taking the witness statements into account unless there was a particular reason to do so.

28. He agreed that his five paragraphs at page 6 (bundle 136) of his report did not consider the fluid balance chart or how long the Claimant was on IV, nor the drinks she had that night nor the absence of entries thereafter nor the Buccastem. He said there was some confusion about the drug records and he received additional drug records later. It was put to him that that could not be right with reference to the as required drugs chart and he must have got the information from there about the morphine. He said that as far as he knew from this he must have omitted the Buccastem for some reason. He had assumed it

was a step down from the Ondansetron. It was pointed out to him that the chart for regular drug therapy it was maintained throughout and there was an initial for the 18th and he agreed that that was the case. He did not accept that that this was careless but it was an error and it was judgemental rather than careless.

29. It was put to him that he had missed the tick in the daily nursing care plan recording nausea at 1800 hours and he said he was sure he had seen it but at the time had not thought it was important enough to refer to it and he was unsure of the exact reason. He was asked whether he had trusted the observation chart for accuracy and reliability and said you had to acknowledge the information as it existed. He agreed that it was for him as an expert to draw the court's attention to it as he had done elsewhere. He was asked whether he now agreed that the observation chart could not really be read consistently with regard to the use of Buccastem and the tick for nausea. He said he was not sure he agreed. There were different observations at different times as was likely. Nausea could come and go. The drugs prescribed could succeed and hence there could be a negative tick after a drug had been given. It was put to him that it was selective to say as he had done and he said yes he admitted he might have missed it.

30. It was put to him that he should have referred to the evidence from the Claimant and her mother and he said it was subjective information and he was trying to draw his report from the objective evidence and the clinical records. He agreed it was a matter of balance for the court.

31. He was asked why at page 136 (page 6 of his report) he had omitted the nursing record at 4.10 on the 18th and he said issues about Particulars of Claim were addressed in the reports and he had not documented all the nursing records and

had tried to select the points relevant to the progress of the patient. He was asked whether he thought there was nothing of objective relevance in the entry for 4.10 on the 18th and said that was his opinion at the time. He was asked whether it was not relevant to note that antiemetics had been given and he said he thought it was just part of the treatment prescribed for the Claimant.

32. It was put to him that he had reviewed the junior doctors' record but said nothing about the codeine and had misinterpreted the squiggle signature and he said that was probably the case. He agreed that the morphine dose of 15 mgs was the largest opiate analgesic the Claimant had and said he thought it was the only oral dose. He agreed it was very difficult to tell from the as required drugs chart which were IV and which were oral. He thought it was the case that two signatures were necessary for intravenous drugs. It was put to him that if one assumed the last three doses of morphine were oral he was wrong about the dose and did not refer to the fact that it was the largest dose of morphine since the operation and it was put to him that this was careless. He said he had not commented on it and he thought he had assumed that the previous three doses were IM. As to his comment at page 32 (bundle page 162) of his report it was unclear why 10 mgs of morphine was administered at 10.40 on 18 February, and whether he would not expect an explanation in the notes he said there might or might not be one.

33. He was referred to the absence of any reference to the requirement of wellness in the same page of his report and also page 7 (of 137) and was asked why he had not referred to "if well" and he said it was not dropped from the picture. Initial comments were made by a first-tier house officer who had been a doctor

for seven to eight months and it was a very common expression to use. He would only read into it that by their normal protocol the nurses would consider she could go home and if there any doubts would get medical assurance.

34. It was put to him that Mr Fiennes had been critical of the note and he said the point was that "well" was a very broad generalisation and it meant if a person was fit to go home by ordinary protocols and having had that kind of surgery. It was put to him that it was at the heart of the claim and he said yes but a strict definition of wellness was what was intended by the note. He agreed that Mr Fraser had said what he meant including adequate oral intake and non-dependency on analgesics. It was put to him that his opinion was on a false premise that he did not understand what was meant by well by Dr Fraser. Professor McMahon said no, in general terms it was accepted to the extent that the person was "self-caring" i.e. sufficiently in control of their pain that painkillers could be used and they could cope in their home environment and there were no issues of blood results which would impair their ability to go home safely. It would have been noted that she could take liquid and sloppy foods adequately. He would not place the emphasise on wellness that Mr Coughlan did and he was not sure that he accepted the definition that was being applied to it. He agreed with what Mr Fraser said that something had to change from when he saw her for the Claimant to be well. He had not rejected the Claimant's account but had not included it. He had considered it but not put it into the report. It was put to him that that amounted to a rejection and that it did not show the factual conflict. He said the report was based on the clinical records. It was put to him that the clinical records on the 18th showed that at and around noon she was non-tolerant of fluids. He said yes on the basis of the

three medical visits. There was clear concern about her ability to take oral fluids and there was the IV suggestion. It was odd that although it was recorded she was unable to tolerate oral fluids or water there was no request for fluid assistance in any way and that gave him some consideration and her inability to drink did not concern the nurses or the doctors on the two visits to take any action on it.

35. It was put to him that that was very trusting and that the clinical records did not show she could go home in an hour. He said that it had been written by a very junior doctor and also there were senior nurses on the ward but there was no concern from them that the Claimant was not taking adequate amounts of fluid. There could have been concern the previous day but there was no nursing concern expressed on the 18th.

36. It was put to him that that the nursing records were irrelevant as on page 22 there was no reference to concerns that she was not drinking and she was unable to take fluids without vomiting and he said they were charged with responsibility to see she was well before discharge and would take seriously inadequate oral intake. It was put to him that they should do, and they should also record proper fluid balance charts. He said that once concern diminished the charts were no longer kept and not completing them indicated a lack of concern about fluid intake. As to whether that contrasted with the evidence he said that was a question of how one read the evidence.

37. He was asked whether he agreed with Mr Fiennes that the upper end of normal was not the equivalent to being ready for discharge and this was a clinical judgment. He said it was a question of timing. If the Claimant had been

properly mobilised that day and by the time of discharge was being considered things might have changed and that it was suitable for her to go home. He agreed there was no evidence that she needed extra pain relief as she was being mobilised. He denied that he was giving answers on the hoof. He said the main issues were fairly clear and there was no evidence that she was unsuitable to be discharged when she was and she was under the supervision of a Senior Sister.

38. He agreed that if the Claimant's evidence was accepted she was not well enough for discharge. It would be inadequate if she kept a spoonful of yoghurt down but no water. As to whether there was no record other than "has had some lunch" of a restoration of ability to have fluid intake he said it depended upon the earlier degree of inability, which was in doubt. He was asked whether there was no evidence of adequate oral intake and said no. A Senior Sister who was later a Ward Manager would not have got it wrong. It was put to him that was not on the evidence and he said it was a question of what you read into what the note intended. It was as much as you would expect to find in the records with regard to such a patient. It was put to him that he did not know what it meant and he said it was a judgment by the person who wrote the note and he agreed he could not know and it could be an HCA.

39. With regard to causation it was put to him that this was a specialist unit and he said yes but he would have been referring in examination-in-chief to the type of unit in Leeds or St George's where there was a particular interest in bariatric surgery. He agreed that they would be held to the same standard but said that nevertheless there was a difference.

40. It was put to him that what he said about causation in his report at page 35 (p. 165 of the bundle) was very brief and he had not asked himself relevant questions such as the Claimant being a patient with a vomiting history and failure to tolerate oral intake with an analgesic requirement and progression to raise CRP from 11 to 50 on the 19th, the failure to make expected post-operation progress, better at retaining fluid but suffering pain on swallowing. He said that it had become more apparent in the last few days and he had not thought the treatment would effectively be different from what had happened on the 20th. It was put to him that that was not the proper approach and contrast to that of Mr Fiennes and he said it was reasonable to infer from the clinical data when she was readmitted on the 20th what would have happened on the 19th and what her condition would have been on the 19th. It was put to him that the proper question was what would have happened if there had been reasonable care when she was retained and he said he was assuming it in the same way and save for the possibility of it happening a day or two earlier he thought some action would have occurred if she had been retained as well as when she was readmitted. It was he said Mr Coughlan's opinion that his approach was inferior to that of Mr Fiennes. He did not necessarily agree. He had addressed it in a slightly different way. He was asked whether he would maintain his views about timing and results set out in answer to question 11 in the joint statement. He said it was difficult to say. She was not so acutely ill and it would not have been urgent investigation and the clinical circumstances were not such as would be a major problem. He agreed with what Mr Fiennes had said that with heavier patients they would suffer more if a leak developed so it was necessary to go in earlier if there were indications, but said it was all in the

context of exactly how ill the patient was and what could happen with another operation so soon after. The index of suspicion was there and it was evidenced by the contrast swallow request. The leak was what you would be suspecting and that was the logical conclusion to the process. Too much was being read by Mr Coughlan into the word "leak".

41. He was referred to what was said in the Kim paper about a reasonable surgeon in such a case acting earlier and he said yes but the context was important. If a person had organ failure and sepsis it was urgent. If on observation the biochemistry was normal apart from the CRP giving suspicion of a leak and the contrast swallow was normal the appropriate step was to keep them under observation and for example have a CT scan and if there were suspicions to continue. To do an operation on the basis of one abnormality and symptoms which could be due to the sleeve itself would be wrong and foolhardy. In this case he would wait until there was stronger evidence of need for operative intervention. If the CT scan two days after the contrast swallow was equivocal and if the CRP was rising then he would have the evidence and the need for an intervention.

42. As regards the duration of the window he said he would come back to the Burgos and Jurowich papers. Only two patients had undergone exploration and suture in the first two days, one satisfactorily and one was in hospital for 30 days and had a stent. None were operated on after the first two days did significantly better. To re-operate within two days there had to be a good reason, for example evidence of frank peritonitis due to a staple line failure or a leak demonstrated by a contrast swallow in the first 24 or 48 hours and the leak

from the staple line from the operation would be revealed. In contrast the Claimant's case was one of a much more gradual evidence of leakage over several days.

43. He was asked whether having invented the procedure in the United Kingdom he had recent experience of post-operation gastric sleeve patients. He said that he had not managed any patients post-operation for about five years and had last done a gastric sleeve he thought six or seven years ago. To his knowledge he had never sutured any failed staple line.

44. He was referred to the Kim paper, which he said was a review, and it was put to him that it was the current state of knowledge. He was asked whether he agreed with Mr Fiennes that this was a case of clinical suspicion which would lead to the conclusion that from the 18th as Mr Fiennes suggests there would be imaging on the 19th and surgery that evening. He disagreed fundamentally with this view. It would be necessary to leave the Claimant until there was stronger evidence to justify the risks of reintervention. It was a balance. You did not have to act on a suspicion and it was a question of the best interests of the patient and if too cavalier or too conservative patients might suffer. He agreed with what had been said in the joint report about anaesthetic risk being an obstacle to a necessary re-exploration and he said yes if necessary and he and Mr Fiennes disagreed about that.

45. He said it was generally the case that with surgical complications the sooner you intervened the better outcome for the patient before organ failure was established but there was nothing like that here. There were normal observations and blood results and she had been investigated on suspicion and it

was appropriate to continue to observe so the suspicions were exonerated or proven and you did not await deterioration but more positive evidence.

46. He was asked whether contemplation of organ failure tipped the balance of necessity and he said that implied that that was the case here but it was important to do so before that happened. It did not come into the chronology of expected events in this case. She was well and it needed a definitive determination of whether reintervention was justified. It would have been achieved by continued observation and investigation. If the CRP rose and the scan was equivocal it would be justified and you could see the direction of travel. Having looked at the dates in Burgos and Jurowich there was no question of saving the staple line after the first 48 hours.

47. It was put to him that he was not prepared to open his mind to Mr Fiennes' view with regards the benefit of going in early which should happen if there was reasonable care. Professor McMahon said that if you needed to go in in the first 48 hours but in a case such as this to encompass the sleeve's swollen area you would have to put stitches in quite deeply and you would narrow the sleeve and the data in the paper suggested it would fail and drainage and control were needed. Suturing would not have prevented leakage. Generally the earlier you intervened the better the outcome. That did not mean there was a significant and greater benefit in going on the 21st or the 22nd. Her condition was not changing much and there was no real deterioration and no significant difference on which day one acted. It was agreed that a fistula would develop and a stent would not be avoided. This was also true for days five, six and seven in contrast to when intervention was carried out when it was a lot worse. If the

CRP was rising she would not have been sent home. When she was operated on there was a question of a degree of development of symptoms and the rise in CRP would be required and clearly something needed to be done. A CT scan could have revealed the problem. There would be no significant difference over a few days when she had the reoperation. It was probable that the few patients in the few post-operative days probably had a mechanical leak. There was not time for this to develop, it could only be explained if there was a defect in the staple line. It was not the case that you would only operate if the staple line was defective. There had to be a logical reason for early intervention and the case that Mr Fiennes referred to was the only one where it had not failed. He had provided his diagrams only to demonstrate the process. With regard to the point put to him concerning the benefits of early exploration as mentioned in Kim he said he did not think so because the process of evolution to the point of surgical intervention took several days. Most people did not come to that and it would not justify an early operation. It was really a question of the soggy mass usually developing before one intervened as it had to do so before the localised leakage that led to intervention. He was asked whether he accepted that conclusion on when the balance for exploration tipped Mr Fiennes closer to what was said in Kim and he said in respect of 48 hours, but the Kim data was based on the two papers and there was no justification for intervening by intervening in 48 to 72 hours. It was basic that intervention had to be as early on as could be for best outcome, but that did not mean you would put the patient to the risk of intervention including creating a leak unless there was sufficient reason and it was a matter of judgment and experience. He did not accept that what Mr Fiennes said was closer to what was concluded in the Kim paper.

48. On re-examination, with regard to the Kim paper Professor McMahon agreed that this was not an acute case. It was not the Kim situation and was not a 48 to 72 hours case. Her electrolytes were normal and the urea not at the top end but well within it and her creatinine was well within a range that was compatible with normal physiology. It did not change before the 18th and the 20th. It was compatible with normal adult physiological health.

49. He agreed that the final paragraph of page 35 (165 in the bundle) of his report described a process after surgery. Academic papers put in concerned surgery within two or three days where there was a frank leak.

50. In response to further questions from Mr Coughlan regarding the pathology results he agreed that the Claimant had drunk 350 mls on the 17th. It was put to him that the bloods on the 18th were unlikely to be deranged and he said yes. There could have been an element of rehydration from the IV but that was stopped 36 hours earlier. If the fluid intake was close to 0 except for the 350 mls he would expect the urea to be at the upper limits of normal. He would expect it to be at the top end of normal and the results indicated adequate oral intake while in hospital. It was put to him that this contrasted with the clinical records and he said there was probably not much vomiting. The electrolytes were normal on the 20th as on the 18th. It was put to him that she was clinically dehydrated and he said yes but it was difficult to judge dehydration, especially in an overweight person. Electrolytes were the same.

ANNEX 8

"**Laparoscopic Sleeve Gastrectomy (LSG)**

a) **Please identify the risks and complications associated with laparoscopic sleeve gastrectomy.**

It was agreed that the risks and complications associated with laparoscopic sleeve gastrectomy include bleeding, staple line leakage, narrowing and stricture formation, gastro-oesophageal reflux and general complications and anaesthetic complications associated with abdominal surgery.

b) **Please comment on the Claimant's pre-operative risk profile.**

It was agreed that on the basis of a body Mass index of 55.6, obstructive sleep apnoea treated with CPAP and asthma, she had a moderately increased risk of death.

Staple line failure

a) **Please explain the mechanism and timing by which staple line failure occurs**

It was agreed that failure of the operative technique to co-apt the tissues to create a sleeve, the selection of an inappropriate size of staple and characteristics of the tissues of the stomach may all contribute to staple line failure, and as a result, staple line leakage. Staple line failure may be associated with mechanical factors at the time of the operation or tissue-related factors such as ischaemia, that can occur immediately or after a period of delay. The important consequence of staple line failure is the development of either frank

leakage leading to peritonitis or the development of a contained localised collection adjacent to the gastric sleeve. The containment can subsequently fail leading to peritonitis.

It was further agreed that the majority of leaks are detected several days after the operation. The experts agreed with the figures quoted in the paper by Kim et al., page 742, final paragraph in column 1.

b) **What are the post-operative clinical indicators of a staple line failure?**

It was agreed that there are both localised and generalised clinical features of staple line failure. Localised features include epigastric pain and pain on swallowing, difficulty with swallowing and vomiting. Generalised features, that may occur somewhat later, include pyrexia, tachycardia, tachypnoea, low oxygen saturation and low urine output.

c) **What are the post-operative imaging indicators of a staple line failure?**

With regard to the detection of failure prior to the development of a frank leak, the experts agreed that poor transit of contrast during a contrast swallow or narrowing of the sleeve might be of significance depending upon the clinical context. CT scan might reveal a collection or unexpected fluid adjacent to the staple line of the sleeve or inflammation in tissues adjacent to the sleeve.

With regard to leaks it was agreed that the sensitivity of a contrast swallow was less than that of a CT scan even when a frank leak was present (see Kim et al. 2015, page 743, column 1). If there is continued suspicion of leakage, despite negative imaging, re-laparoscopy is the most reliable diagnostic aid.

d) **How is a staple line failure detected post-operatively?**

It was agreed that staple line failure can be detected post-operatively by the prompt resort to radiological investigations on the basis of clinical suspicion. If the suspicion continues to exist despite negative radiological investigations resort to re-laparoscopy provides the most reliable diagnosis.

e) **How useful is imaging in the identification of the early stages of staple line failure post-operatively? Please explain your answer.**

The experts refer to their response to c) above. As staple line failure progresses, it would be expected that the sensitivity of imaging would increase. Please see Kim et al. 2015.

f) **Please review the ASMBS Statement attached at appendix 1: Consider the paragraph under heading Radiological evaluation versus exploration for suspected GI leaks after SG at page 743, in particular:**

> **'As with GI (gastrointestinal) leak after GB (gastric bypass) laparoscopic or open re-exploration is an also appropriate diagnostic option, regardless of the feasibility of obtaining a post-operative imaging test when a GI leak is suspected. Exploration is characterised by a higher sensitivity, specify and accuracy than any other post-operative test to assess for leak and should be considered to be the definitive assessment for the possibility of leak when the patient is clinically unstable, or in the scenario wherein alternate diagnoses have been excluded and/or clinical suspicion remains.'**

Please consider this statement, and the rest of the paper and any other relevant studies, and provide your comments.

As surgeons, we are in agreement with the opinion expressed in the quotation.

g) **In your view was the Claimant clinically unstable when she was discharged on 18 February? Please explain your answer.**

The experts agreed that clinical observations were all within the accepted normal range. All laboratory values lay within the expected range for a patient on the second day after sleeve gastrectomy. It was agreed that it was unusual for opiate analgesia to be required on the second post-operative day of the sleeve gastrectomy.

AGF was of the opinion that the analgesic requirements were greater than expected on 18 February. MJM, whilst agreeing that most patients do not require opiate analgesia on the second post-operative day, thought it important to appreciate that there is considerable variation in the requirement for analgesia after sleeve gastrectomy so that in the context of her general progress, analgesic needs were not an indication of instability.

It was agreed that it would be substandard to send a patient home after sleeve gastrectomy if they were unable to eat and drink. AGF was of the opinion that this was an important context to the analgesic requirements. MJM considered that some patients after sleeve gastrectomy or gastric bypass experience difficulty drinking water even though they can manage other foods, such as yoghurt, without difficulty.

h) **In your view, should there have been clinical suspicion of a GI leak on 18 February 2013? Please explain your answer.**

The experts agreed that there were no features of overt staple line leak on 18 February.

AGF was of the opinion that if the Claimant was substantially unable to take anything by mouth the development of staple line failure had to be considered.

i) **Earlier in the paragraph referred to in (h) above it states: 'In patients with clinical signs or symptoms of a suspected leak after SG ……most studies recommend obtaining a CT with oral and IV contrast as the method of choice for diagnosis of a leak in patients who show signs and symptoms suggestive of a leak but remain clinically stable.**

In your view, based on the Claimant's presentation on 18 or 19 February was laparoscopic or open exploration mandated by 19 or 20 February 2013? Please explain your answer.

The experts agreed that their understanding of the quotation was that in patients with signs and symptoms suggestive of a leak, but who were clinically stable, CT was the imaging modality of choice compared to a contrast swallow.

It was agreed that the clinical presentation 19 February can be inferred from the progression from the 18th to the 20th.

AGF was of the opinion that clinical/laboratory worsening on the 19th would have raised sufficient suspicion to warrant investigation. He was further of the opinion that in the presence of such suspicion he would not have been reassured

by negative findings from investigations with a known false negative rate. If his clinical suspicion had persisted after imaging he would have undertaken laparoscopy.

MJM was of the opinion that the Claimant's condition on 18 February and the expected condition on 19 February would not have indicated the need for re-laparoscopy. There may have been concerns about her ability to swallow, and had she been kept in hospital it is probable that a contrast swallow would have been carried out, but may not have been performed until the 20th or 21st.

j) **What would be the risks of a laparoscopic or open exploration to this Claimant?**

The experts agreed that there was no indication for an open exploration, and it is improbable that the findings of a laparoscopic exploration would have indicated the need for open surgery.

It was agreed that the Claimant would have been exposed to the risks of further general anaesthetic and laparoscopic exploration. In practice, these risks would not be an obstacle to a necessary re-exploration.

MJM was of the opinion that if exploration was carried out without due suspicion that there was a defect in the staple line, it would expose the patient to the risk that a defect could be caused in an otherwise well healing staple line.

k) **Is there a reasonable and responsible body of bariatric surgeons who would not carry out a laparoscopic or open exploration based on the Claimant's presentation on 18, or 19 February 2013?**

It was agreed that the Claimant's presentation on the 18th February was not such that exploration was indicated.

AGF was of the opinion that it would have been reasonable not to re-explore on the 19th as long as alternative close-monitoring modalities were in place.

MJM considered that the Claimant's condition 19th February would not have indicated the need for re-exploration.

l) **Once identified, how is a staple line failure treated?**

It was agreed that the treatment of staple line failure is reviewed in the article by Kim Al (2015), page 743, including the role of very early reoperation.

m) **Please comment on the importance of the timing of treatment and the impact of any delay in treatment.**

In general principles, the earlier staple line failure is treated the better the outcome and the lower the risk of complications, including death.

Recovery/Post Operative Care following LSG

a) **What is the expected recovery process following an uneventful LSG procedure?**

It was agreed that an uncomplicated recovery would be characterised by discharge from hospital on the second or third post-operative day, the patient clearly tolerating adequate amounts of fluid and food with observations that lay within the expected range.

b) **What is the range of variation in the recovery process between different patients and, viewed prospectively, was the Claimant's presentation within or outside this range of normal patient presentations?**

It was agreed that there is significant variability in the recovery process amongst different patients. If the Claimant was substantially unable to take adequate amounts of food and drink on the second post-operative day, and she still had high analgesic requirements, her presentation would have been at, or close to, the limit of the range expected for a normal recovery.

c) **Please explain the role of the Bariatric Surgeon in the post-operative care.**

It was agreed that the role of the bariatric surgeon, in the light of their specialist knowledge, is to monitor and supervise the recovery process and to ensure that there is an appropriate response to clinical events

d) **When should a reasonably competent Bariatric Surgeon undertake medical review of a patient in the post-operative period? Is there any mandated period for review?**

It was agreed that medical review should be undertaken by a bariatric surgeon daily, or more frequently if events indicate it. This would be a recognised minimum standard.

e) **Surgery was completed at 13.10 on 16 February 2013 and the Claimant remained on the post anaesthetic care unit under close observation until 17.50. In these circumstances in your view would it be a breach of duty for the bariatric surgeon not to assess the patient until the following day? Please explain your answer.**

It was agreed that if the Claimant was seen by the surgeon in the recovery room after completion of the operation it would not be a breach of duty to delay further review until the following morning.

f) **What are the post-operative indicators that are cause for concern that a patient's recovery is not in accordance with the expected recovery process?**

Please see response to question 7b.

g) **Please comment on the role of the MEWs score in the post-operative period. Can it be relied upon alone to rule out complications?**

It was agreed that the purpose of the MEWS score in the post-operative period is to enable the nursing staff to know when to escalate the level of care and attention to more senior members of staff.

It was agreed that a low MEWS cannot be relied on to rule out complications.

BREACH OF DUTY

The Claimant's post-operative clinical picture

a) **16/17 February**

Please consider the Claimant's clinical picture (including but not limited to observations, analgesic requirements, any anti-emetic requirements, fluid intake and output, nutritional intake, reported symptoms including nausea and vomiting) on the following occasions:

- **16 February 2013 – The day of surgery**

- **17 February 2013 – First post-operative day**

i) **On each of the occasions set out above, please consider whether the Claimant's clinical picture was in accordance with the expected recovery profile.**

It was agreed that on 16 February the clinical picture was consistent with the expected recovery profile.

AGF was of the opinion that on the 17th, the first post-operative day, the Claimant's recovery was still within a normal range but warranted careful monitoring. MJM considered that the Claimant's recovery was within the expected range on the 17th.

b) **18 February – Second Post-Operative Day.**

i) Please consider the Claimant's clinical picture on the second post-operative day including observations, analgesic requirements, anti-emetic requirements, fluid intake and output, nutritional intake and reported symptoms including nausea and vomiting.

In doing so, please consider the contents of the medical records and the witness statements of Mr Fraser, Mr Menon, the Claimant and Nirmla Kalair (the Claimant's mother).

Please consider whether the Claimant's clinical picture was in accordance with the expected recovery profile and comment on the standard of care provided by those treating the Claimant.

It was agreed that on the 18th the Claimant's recovery lay within the expected range with the exception of analgesic requirements and the ability to take fluid orally. We note the discrepancy between the nursing record and the statements referred to above and it is for the Court to decide on the facts. If she was able to tolerate adequate oral intake, it was satisfactory to allow her to go home.

ii) Please review the medical review notes timed at 10.30, 12.00 and untimed entry from Mr Fraser. Please comment on the Claimant's tolerance of fluids as noted in these entries.

It was agreed that all three entries document difficulties with fluid intake. MJM noted that two of the entries referred specifically to water.

iii) In an untimed note of a review by Mr Fraser it is noted that the Claimant was 'unable to keep down H20 without vomiting' … 'Plan- 1. Enoxaparin for 2 weeks 2. Home today if well. 3. 1 month follow up with Mr Menon 4. Fluids only 5. point advised not to fly in aeroplane for 6 weeks …'

In the nursing note timed at 14.00 it is noted that during his ward round Mr Fraser noted that the Claimant could go home 'if well'.

Was the Claimant's clinical picture on 18 February consistent with her being 'well'?

It was agreed that in the context of the note 'well' included adequate oral intake.

iv) There is a factual discrepancy as to whether the Claimant was able to tolerate food prior to discharge. The nursing note 14.00 states '… Has had some lunch and not vomited …' whereas the Claimant's account is that she had one spoonful of yoghurt and immediately vomited (see paragraph 14 of the Claimant's statement). This is a factual issue to be determined by the Court. Please comment on the Claimant's clinical picture, and in particular whether she was 'well', if the Court were to make a finding of fact as follows:

- **The Claimant had some lunch and did not vomit; or**

  It was agreed that this would be consistent with the description 'well'.

- **The Claimant had one spoonful of yoghurt and vomited.**

  It was agreed that this would not be consistent with the description 'well'.

Discharge

a) Was there any cause to suspect a potential staple line leak prior to the Claimant's discharge? Please explain your answer.

It was agreed that if she was able to tolerate adequate oral intake there was no material cause to suspect a potential staple line leak, but if she was unable to tolerate oral intake that possibility had to be considered.

b) Was it appropriate to discharge the Claimant on 18 February? Please explain your answer.

It was agreed that it was reasonable to discharge the patient as long as there was adequate oral intake.

c) If your answer to b) is no, please set out what you consider would have been appropriate action on 18 February?

It was agreed that if the Claimant had been retained in hospital because of concern about the adequacy of oral intake she would have been monitored clinically and by laboratory investigations. Unless she progressed in a satisfactory manner imaging would have been carried out as discussed above.

CAUSATION

Development of the staple line leak

a) **On the balance of probabilities, when did the Claimant's staple like (sic) leak start to develop?**

It was agreed that the staple line failure was a progressive process that in all probability had begun to develop by 20 February as evidenced by the relatively modest rise in C-reactive protein.

b) **On the balance of probabilities, when did a frank leak develop?**

It was agreed that on the basis of the clinical history and the level of C-reactive protein on 3 March, it is probable that the frank leak developed on 1 March.

Clinical Picture post 18 February

Please consider the Claimant's likely clinical picture had she been kept in hospital on 18 February, in particular on the balance of probabilities whether there would have been any improvement or deterioration.

It was agreed that it is probable that if she had been retained in hospital on 18 February she would have progressed to be able to drink liquids but to do so would have been painful, as evidenced by her condition on readmission on 20 February.

Post-operative investigations

Radiology expert evidence has concluded that on the balance of probabilities, 'a CT scan performed on post-operative 2 or 3 (18 or 19 February) is likely to have shown a small area of fluid in the area around the operation, which would have been judged to be within normal limits for the patients post-operative status' (Report of Dr Tolan paragraph 2.2.6).

a) **Would a reasonably competent Bariatric Surgeon have been reassured by negative findings of imaging in the Claimant's case on post-operative day 2-3? Please explain your answer.**

AGF considered that he would have been relatively reassured by negative findings in the context of the patient's overall clinical condition.

MJM considered that he would have been reassured by negative findings given the known clinical condition of the Claimant on 18 and 20 March.

b) **If your answer to a) is no, please set out what you consider would have been appropriate action following negative findings of imaging, including any subsequent investigations and/or treatment (if any).**

It was agreed that if the answer had been no, i.e. the result of imaging had not provided reassurance, further monitoring and investigation would have been carried out in a manner set out by Kim et al 2015.

Subsequent Treatment

a) **Had laparoscopic repair of the staple line been performed on post-operative day 3 or 4 (19 or 20 February 2013), on the balance of probabilities would full failure of the staple line have been prevented?**

AGF was of the opinion that intervention on the 19th offered a reasonable prospect of preventing full staple line failure.

MJM considered it improbable that failure of the staple line would have been prevented by intervention on the 19th or 20th February.

b) **Had laparoscopic repair of the staple line been performed on post-operative day 3 or 4, please comment on the Claimant's likely outcome and whether any of the subsequent complications including the development of a fistula, oesophageal stenting, pulmonary embolism and extensive recovery period would have been avoided.**

It was agreed that even if primary repair of the staple line was unsuccessful it is probable that the Claimant would have had a far shorter stay in hospital and that, whilst a fistula might have developed, it would have been 'controlled'. It

is difficult to know whether or not a stent or stents would have been avoided. It is probable that the pulmonary embolism would have been avoided.

Statement of Truth

We reaffirm the limitations set out and the Statements of Truth given in our respective Liability Reports and aver that we have not been instructed to avoid reaching agreement or to otherwise defer from doing so on any matter that is within our competence.

We can confirm that we have made clear which facts and matters referred to in this report are within our own knowledge and which are not. Those that are within our own knowledge we confirm to be true. The opinions we have expressed represent our true and complete professional opinions on the matters to which they refer.

[Signed]	[Signed]
Alberic GTW Fiennes	Michael J McMahon
April 27th 2019	April 27th 2019

Appendix

1. **Kim, Julie et al (2015), ASMBS position statement on prevention, detection and treatment of gastrointestinal leak after gastric bypass and sleeve gastrectomy, including the roles of imaging, surgical exploration, and nonoperative management.**"