



Neutral Citation Number: [2026] EWHC 1284 (KB)

Case No: KB-2023-001713

IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 29/05/2026

Before:

HHJ RICHARD ROBERTS,
SITTING AS A DEPUTY HIGH COURT JUDGE

Between :

MR ANDREW ALEXANDER
- and -
(1) HCA INTERNATIONAL LIMITED
(2) DR DAVID REFFITT

Claimant

Defendants

Mr Liam Duffy of Counsel (instructed by **Irwin Mitchell**) for the **Claimant**
Mr Jason Cox of Counsel (instructed by **DAC Beachcroft LLP**) for the **First Defendant**
Mr Andrew Perfect of Counsel (instructed by **CMS Cameron McKenna Nabarro Olswang LLP**) for the **Second Defendant**

Hearing dates: 16, 17, 18 and 20 March 2026

Approved Judgment

This judgment was handed down remotely at 10.30am on 29 May 2026 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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HHJ RICHARD ROBERTS

HHJ Richard Roberts:

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Introduction

1. This is the trial of the Claimant's claim for damages for clinical negligence arising out of an endoscopic retrograde cholangiopancreatography procedure (ERCP) performed on 16 July 2019 by the Second Defendant, a Consultant Gastroenterologist, at London Bridge Hospital (the Hospital). The Claimant was a private patient at the Hospital, which is owned and operated by the First Defendant.
2. Mr Liam Duffy of Counsel appears on behalf of the Claimant, Mr Jason Cox of Counsel appears on behalf of the First Defendant and Mr Andrew Perfect of Counsel appears on behalf of the Second Defendant. I am grateful to all Counsel for their skeleton arguments and their closing written submissions.
3. There are the following bundles before the Court:
 - i) Red bundle: core bundle in 1 volume
 - ii) Core bundle of medical records for trial (core bundle)
 - iii) Green bundle: literature bundle in 2 volumes
 - iv) Black bundle: medical records bundle in 9 volumes
 - v) Authorities bundle
 - vi) First Defendant's authorities bundle.
4. I will refer in this judgment to the bundles by way of colour (R, G or B) or core bundle, tab and page number.
5. There are transcripts of each day of the trial.

Limitation

6. In the amended Defence of the First Defendant, dated 22 January 2024, it was alleged at paragraphs 5-7 (R/12/p. 80) that the Claimant's claim was statute barred. However, at the outset of the trial, Mr Cox indicated that the First Defendant was not pursuing a defence that the claim was statute barred.

Quantum

7. During his opening of the trial, Mr Duffy informed the Court that quantum had been agreed, subject to liability, in the sum of £550,000.

Evidence

8. The Court heard lay evidence from:
 - i) The Claimant, who has provided a witness statement, dated 6 November 2024 (R/23/p. 189-198) and a supplementary witness statement, dated 16 September 2025 (R/25/p. 207-212)
 - ii) Phillip Deppeler, the First Defendant's Endoscopy Manager, who has provided a witness statement dated 10 March 2025 (R/27/p. 227-232)
 - iii) Nurse Mondido, who has provided a witness statement dated 11 March 2025 (R/28/p. 233-238).
 - iv) The Second Defendant, who has provided a witness statement dated 4 December 2024 (R/26/p. 213-226)
9. The Claimant served a witness statement from his wife, Gay Mitchell, dated 6 November 2024 (R/24/p. 199-206), but she was not called to give evidence.
10. The First Defendant served a witness statement from Nurse Ferrari, dated 9 March 2025 (R/29/p. 239-241), and a witness statement from Hazel Davies, Senior Associate Solicitor with the conduct of the claim on behalf of the First Defendant (R/30/p. 245-248) but neither Nurse Ferrari nor Ms Davies were called to give evidence.
11. The Court heard expert evidence from:
 - i) Professor Ian Gilmore MA MD FRCP, Consultant Physician and Gastroenterologist on behalf of the Claimant. Professor Gilmore has provided a report, dated September 2025 (R/31/p. 251-269)
 - ii) Dr Jeremy Woodward MA MB BChir FRCP PhD, Consultant Gastroenterologist on behalf of the Second Defendant. Dr Woodward has provided a report, dated October 2025 (R/35/p. 365-422)
 - iii) Dr Michael G. Anderson MD FRCP, Consultant Physician and Gastroenterologist on behalf of the First Defendant. Dr Anderson has provided a report, dated 31 October 2025 (R/36/p. 423-434).
12. There is a CPR Part 35 joint statement by Professor Gilmore, Dr Woodward and Dr Anderson, dated December 2025 (R/40/p. 517-528).
13. The experts in surgery provided the following expert reports and joint statement:
 - i) Mr Graeme J Poston DSc MB MS FRCS (Eng) FRCS (Ed), Consultant Surgeon on behalf of the Claimant, dated 16 May 2023 (R/32/p. 271-282)

- ii) Mr John Hartley, Consultant Surgeon on behalf of both Defendants, dated December 2025 (R/39/p. 491-516)
 - iii) Joint statement of Mr Poston and Mr Hartley, dated February 2026 (R/42/p. 541-544).
14. The experts in diabetes and endocrinology and the experts in interventional radiology provided the following expert reports and joint statement:
- i) Dr Ken H Darzy MB CHB FRCP & MD, Consultant Physician, Diabetologist & Endocrinologist on behalf of the Claimant, report dated September 2025 (R/33/p. 283-342)
 - ii) Dr John Reidy MBBS FRCP FRCR, Consultant Vascular and Interventional Radiologist on behalf of the Claimant, report dated September 2025 (R/34/p. 344-363)
 - iii) Dr David A Scullion MBBS MRCP FRCR, Consultant General Radiologist on behalf of the First Defendant, report dated December 2025 (R/37/p. 435-450)
 - iv) Dr Paul G McNally MD FRCP, Consultant Physician on behalf of both Defendants, report dated December 2025 (R/38/p. 451-490)
 - v) Joint statement of Dr Darzy and Dr McNally, dated 25 February 2026 (R/41/p. 529-539).
15. The experts in surgery, the experts in diabetes and endocrinology and the experts in interventional radiology were not called to give evidence at trial.

Duty of care

16. The First Defendant was responsible for clinical, nursing and other staff at the Hospital and is vicariously liable for the negligent acts and omissions of staff committed within the course of their employment.
17. The Second Defendant and the staff of the First Defendant owed the Claimant a duty to treat him with reasonable professional skill and care.
18. The First and/or Second Defendant owed the Claimant a concomitant duty in contract.
19. It is agreed that as stated in the amended Defence of the First Defendant (R/12/p. 81),
- “10.1 It was the responsibility of the Second Defendant alone to decide what medication the Claimant required prior to, during or after the ERCP procedure on 16th July 2019.
- 10.2 It was the responsibility of the First Defendant’s nursing staff to administer medication as prescribed by the Second Defendant.”

Background

20. The Claimant was born on 27 February 1968. In July 2019 he was aged 51. He is now aged 58.
21. In May 2019 the Claimant suffered intermittent upper right abdominal pain.
22. On 28 May 2019, the Claimant underwent an ultrasound scan of his abdomen at the Hospital.
23. On 10 June 2019 he was seen by Mr Davies, Consultant Surgeon. Mr Davies referred the Claimant to the Second Defendant for further investigation in advance of possible gallbladder surgery for gallstones.
24. On 14 June 2019 the Claimant had a consultation with the Second Defendant as an outpatient. There was a discussion about endoscopic retrograde cholangiopancreatography (ERCP). An ERCP is an investigation of the biliary tract which is performed by passing an endoscope through the mouth and past the stomach to the biliary tree. If stones are present, they can be removed.
25. On 18 June 2019, the Claimant had a Magnetic Resonance Cholangiopancreatography (a type of MRI) scan at the Hospital, which showed a stone in the common bile duct. The Second Defendant advised that an ERCP be performed.
26. On 16 July 2019, the Claimant underwent an ERCP at the Hospital, performed by the Second Defendant. The ERCP revealed an 8mm stone in the distal common bile duct, which was removed. Also listed as being present at the procedure were the First Defendant's staff: Nurses Ferrari, Mondido and Bouwer. The Defendants have not served a witness statement from Nurse Bouwer. This was the only ERCP which the Second Defendant carried out at the Hospital that year (R/26/p. 215 at paragraph 20).
27. The Second Defendant says in his witness statement (R/26/p. 217),

“34. ... It is my usual practice to always prescribe Diclofenac either before or during a ERCP procedure in all cases in order to reduce the risk of post-procedure pancreatitis”
28. On the Pre-Procedure Checklist, signed by Nurse Ferrari, one of the entries is “Prescribed Pre medication given” (core bundle/7/p. 791). None of the options (Yes No N/A) are selected. The columns “1st check 1st pre-procedure check” and “3rd check on entry to the anaesthetic room” are both initialled.
29. The First Defendant's “ERCP under GA” protocol requires oral 750mg Ciprofloxacin to be given two to three hours before the procedure (core bundle/6/p. 782).
30. The WHO Surgical Safety Checklist, Endoscopy Only, dated 16 July 2019, contains sign in and sign out columns (core bundle/7/p. 793). The sign in is timed at 16:46 and the sign out is timed at 17:55. The sign out is signed by Nurse Bouwer. The sign in states,

“Has Antibiotic prophylaxis been given?”

Yes ciprofloxacin.”

This entry is incorrect. Ciprofloxacin had not been administered at this time.

31. Fifteen to twenty minutes before the procedure, the Claimant was consented by the Second Defendant and a consent form was signed by the Second Defendant and the Claimant (core bundle/5/p. 779-780). The box “The procedure will involve rectal administration of drugs” is not ticked. Nor are the boxes stating that the procedure will involve general and/or regional anaesthesia or sedation ticked.
32. If Diclofenac had been prescribed, it would have had to have been brought from the ward or pharmacy, as it is not stored in theatre (R/27/p. 228 at paragraph 5 and R/29/p. 240).
33. There is an Endoscopy Department Drug Prescription and Administration Chart (R/26/p. 266). In the First Defendant’s Part 18 response, the First Defendant says (R/14/p. 91),

“In relation to the First Defendant’s endoscopy department drug prescription and administration chart:

a) Are the listed drugs part of a template available for use for every endoscopy or are the individual medications added manually to the drug chart ahead (sic) each procedure?

Response: Added manually.

b) If the latter:

i. When are the drugs entered on the chart?

Response: After the procedure.”

34. However, in evidence the First Defendant’s Endoscopy Manager, Mr Deppeler, said that the Drug Prescription and Administration Chart is a pro forma document (transcript 16.03.26, p. 40-41),

MR DUFFY: My understanding from the first defendant's Part 18 response is that this document is not a pro forma, and I'll just explain what I mean by that.

MR DEPPELER: Mm-hmm.

MR DUFFY: These particular drugs we see here are not pre-populated on this document; is that right?

MR DEPPELER: These are pre-populated on this document.

MR DUFFY: They are pre-populated?

MR DEPPELER: Yes.

MR DUFFY: So for every endoscopy, there is a one-page document with these drugs pre-populated on it; is that what you're saying?

MR DEPPELER: Yes.

35. This Drug Prescription and Administration Chart is a pre-printed list which is completed by hand. There is a pre-printed list of Oxygen, Sodium Chloride, Midazolam, Fentanyl and Xylocaine Spray, which are recorded in handwriting as having been prescribed and administered between 16:48 and 16:51. The Second Defendant's initials appear beside each prescription and in the "given by" box. The initials in the "checked by" box appear to be "MB", potentially Nurse Meryl Bouwer.
36. The First Defendant's position is that it was for the Second Defendant to enter the medication manually on the Drug Prescription and Administration Chart (R/14/p. 91 at paragraph 1).
37. The non-steroidal anti-inflammatory drug (NSAID) Diclofenac is not recorded in the Drug Prescription and Administration Chart as having been prescribed or administered.
38. The Short Stay Drug Chart, dated 16 July 2019, does not state that the Claimant was prescribed Diclofenac (core bundle/10/p. 2688). The Short Stay Drug Chart only lists post-procedure Ciprofloxacin, timed at 19.00.
39. In the Second Defendant's ERCP report, compiled on 16 July 2029 at 17:53, it is stated under "Premedication": "Diclofenac (PR) 100mg".
40. The electronic Medication Discharge Summary completed by Nurse Bouwer on 16 July 2019 at 18:01, six minutes after she signed the sign out on the WHO surgical safety checklist, does not list Diclofenac (core bundle/9/p. 996-998).
41. Nurse Bouwer recorded in the electronic Medication Discharge Summary that the Claimant was prescribed 40mg Buscopan. It is common ground that the Claimant was not prescribed or administered Buscopan. In cross-examination the Second Defendant said (transcript 16.03.26, p. 122-123),

"MR DUFFY: And if you look at 997, so over the page, the top entry is buscopan here, entered by Nurse Bouwer, but I think it's uncontroversial that that wasn't given at all; is that right?

SECOND DEFENDANT: Yes, and I would never give 40 mg buscopan. That would be a very high dose.

JUDGE ROBERTS: So is this a wrong entry?

SECOND DEFENDANT: I think it is because -- ... I didn't give buscopan. I haven't recorded it."

42. It was noted over an hour after the ERCP had been completed that the Claimant had not been given 750mg Ciprofloxacin as he should have been in compliance with the First Defendant's protocol. The Resident Medical Officer (RMO) on call, RMO Clark-

Morgan, provided a written prescription for Ciprofloxacin in the Short Stay Drug Chart at 19:00 (core bundle/10/p. 2688). RMO Clark-Morgan's note says (core bundle/4/p. 625),

“RMO Clark-Morgan

Approx 18:40 – called from ward.

Pt post ERCP – no Cipro pre-procedure as per protocol

→ NS called Con to check → happy to follow protocol.

P start 750mg Cipro tonight before d/c (PO [orally])

[illegible] for Cipro 500mg BD (2 doses) (PO [orally]).”

43. The First Defendant's “ERCP under GA” protocol requires oral 750mg Ciprofloxacin to be given two to three hours before the procedure (core bundle/6/p. 782). However, the Second Defendant admitted in cross-examination that the Claimant had not been given Ciprofloxacin pre-procedure, even though the WHO Surgical Safety Checklist sign in at 16:46 stated that it had been given. He said (transcript 16.03.26, p 125),

“The resident medical officer, Clark-Morgan, called from the ward post the ERCP: ‘No cipro given pre-procedure’. So she gave me a ring, I said, ‘Yes, give stat dose now, and then two further doses’, yes.”

44. At 21:30 the Claimant was discharged from the Hospital. At around 23:40 the Claimant's wife contacted the Hospital. She reported that the Claimant was suffering from abdominal pain. Advice was given to take simple analgesia and observe.
45. On 17 July 2019 at 02:29, the Claimant attended the Accident & Emergency Department at University Hospital Lewisham with severe abdominal pain. Severe acute necrotising post ERCP pancreatitis was diagnosed and he was admitted. He was initially managed by the Surgeons of Lewisham & Greenwich Hospital and the Clinical Critical Care Outreach Team.
46. On 19 July 2019 the Claimant was admitted to the Critical Care Unit as his condition had deteriorated and a CT scan showed acute necrotising pancreatitis. He required intravenous feeding, artificial ventilation, haemofiltration (a form of dialysis) and showed evidence of multi-organ failure.
47. On 13 August 2019 the Claimant was transferred to King's College Hospital, under the care of the Biliary Surgeons at the Regional Hepato-Pancreato-Biliary Centre.
48. On 14 August 2019 the Claimant underwent surgery because of deteriorating sepsis. At surgery, he was found to have a perforated colon with gross faecal contamination and peritonitis and was severely unstable. A double-barrelled ileostomy was created.
49. The Claimant was discharged from the Intensive Care Unit at King's College Hospital on 31 August 2019 but suffered intestinal bleeding the following day. This was thought

to be due to a pseudo aneurysm of the gastroduodenal artery adjacent to the pancreas, which was then embolised.

50. On 13 November 2019, having spent almost four months in hospital, the Claimant was discharged from King's College Hospital. However, he was readmitted with a further gastrointestinal bleed approximately three days later. He underwent endoscopy and angiography, which were unable to identify the source of the bleeding, but there was concern about the risk of developing a pulmonary embolism and an inferior vena cava (IVC) filter was placed.
51. This IVC filter has not been removed and remains in situ. Mr Poston says in his report at paragraph 7.5 (R/32/p. 280), "It is my opinion that while deferring to experts in Interventional Radiology, it would now be very difficult, if not impossible to remove this filter".
52. The Claimant's condition improved and he was able to return to part-time work.
53. On 17 July 2020 an attempt was made to reverse the stomas at the Hospital. However, this was abandoned because of significant blood loss of two and a half litres and closure of the stomas was not attempted. On 18 July 2020 a further re-look laparotomy was carried out. On 19 July 2020 a colonic re-anastomosis was performed, with a covering loop ileostomy on 21 July 2020. However, a further CT scan on 3 August 2020 showed that there was a splenic and partial superior mesenteric vein thrombosis resulting in left-sided portal hypertension (high pressure within the portal venous system). The Claimant was discharged on 8 August 2020.
54. In October 2020 the Claimant developed an enterocutaneous fistula (communication between the gut and the skin). He was placed on home intravenous feeding to manage this condition.
55. The Claimant required a further admission with an acute hyperglycaemic state due to having developed diabetes necessitating Insulin treatment.
56. On 11 July 2021 the Claimant underwent a successful operation to close the fistula and reconnect the small bowel to the sigmoid colon. Following his recovery from this operation, the Claimant was able to return to full-time work.
57. Mr Poston says in his report (R/32/p. 277 and 280),

"6.12. As a consequence of loss of his colon and the anastomosis of his ileum to his sigmoid colon, whereas before the ERCP his bowels were quite regular opened daily, but now are opened five to six times a day, including once or twice at night and this diarrhoea follows no pattern, and is not related to anything he eats.

...

7.3 ... has to plan his day around toilet access and will do so for the foreseeable future, if not forever."

58. There is a colour photograph showing the Claimant's scarring (R/32/p. 279). Mr Poston says at paragraph 6.17 of his report (R/32/p. 278),

"On examination of the abdomen, there is a 30cm upper abdominal midline incision with poor scarring in the upper central part (the site of the fistula) in addition to a transverse extension of some 20cm on the right side and a further 10cm scar in the lower abdomen at the site of the mucous fistula (see Figure One). These scars are soundly healed with no evidence of incisional hernia."

59. Regarding prognosis, Mr Poston says at paragraph 8.1 (R/32/p. 280),

"It is now nearly some four years since the episode of post-ERCP acute pancreatitis, complicated by necrotising pancreatitis and it is my opinion that whatever recovery his pancreas was going to make (both endocrine and exocrine) has now occurred and his ongoing pancreatic endocrine insufficiency and pre-diabetic state are now permanent. Therefore, he will require long-term Creon for the rest of his life and deferring to Experts in Gastroenterology, Cholestyramine treatment for his putative bile salt malabsorption."

60. Mr Poston says in his report at paragraphs 8.2 to 8.4 (R/32/p. 280 - 281) that the Claimant is at a 5% lifetime risk of developing an incisional hernia and a 10% chance of developing acute adhesive small bowel obstruction. If he developed such a small bowel obstruction, this would require hospital admission, and there would then be a 10% chance of the Claimant requiring emergency surgery and the creation of further stomas and postoperative admission to Intensive Care, before further surgery some months later to reverse the stomas.

61. Mr Duffy says in his opening skeleton argument,

"19. The most significant complications of C's PEP are that he has altered bowel function and has developed type 3c diabetes. Diabetes was first apparent on 8 May 2021 when he required admission for an acute hyperglycaemic state. He is now insulin dependent with a reduced life expectancy and at a risk of diabetic complications."

Issues

62. In this case there are the following issues:

- i) Did the Second Defendant provide a written prescription to the First Defendant to administer 100mg Diclofenac?
- ii) Did the Second Defendant give an oral instruction to the First Defendant's nurses to administer 100mg Diclofenac?
- iii) Was 100mg Diclofenac administered to the Claimant perioperatively?

- iv) On the balance of probabilities, was the Claimant's post-ERCP pancreatitis (PEP) caused by the failure to administer rectally 100mg Diclofenac?
- v) Alternatively, on the balance of probabilities did failure to administer 100mg Diclofenac rectally make a material contribution to the Claimant's pancreatitis?

Questions arising out of the first two issues

63. The following questions arise out of the first two issues:

- i) Should the Claimant have been advised that Diclofenac would be administered rectally?
- ii) Was the Claimant advised at his consultation on 14 June 2019 that Diclofenac would be administered rectally if he underwent an ERCP?
- iii) Should the Claimant have been advised as part of the consenting process on 16 July 2019 that Diclofenac would be administered rectally?
- iv) If the Claimant had been informed on 16 July 2019 that Diclofenac would be administered rectally, would he remember it?
- v) Was the Claimant advised on 16 July 2019 that Diclofenac would be administered rectally?
- vi) Must a written prescription be given by the Second Defendant to the First Defendant to administer Diclofenac?
- vii) Did the First Defendant's nurses administer Diclofenac?
- viii) Did the First Defendant's nurses input pre-medication into the Second Defendant's ERCP report?
- ix) Would the Second Defendant's ERCP report be used as a nursing record of medication administered to the Claimant?
- x) What is the significance of antibiotic prophylaxis Ciprofloxacin being recorded as administered when it was not?
- xi) What is the significance of Buscopan being recorded on the electronic Medication Discharge Summary when it was not given?

Consultation with Second Defendant on 14 June 2019

64. The Claimant says in his supplementary witness statement, dated 16 September 2025, that at his consultation with the Second Defendant on 14 June 2019, he was not advised that he would be given rectally a non-steroidal anti-inflammatory. He says (R/25/p. 208),

“5. I recall attending a pre-operative consultation with Dr Reffitt in his clinic on 14 June 2019. I can remember a discussion about the ERCP and he advised me that although there was some risk,

it was a generally safe procedure. It is true that I had an understanding of some risk of pancreatitis before the procedure, but there was no discussion about guarding against or mitigating that risk, via suppository or indeed by any other means. At the time of the procedure, I was aware of what a suppository was and so I think it would have stuck in my mind if I was told about needing this, as it would have been a lot more significant, and somewhat more alarming, to hear that I would be receiving medication per rectum.”

65. The Second Defendant refers to his consultation with the Claimant on 14 June 2019 at paragraphs 22 to 24 of his witness statement, dated 4 December 2024. The Second Defendant does not say that he advised the Claimant that the Claimant would be given an NSAID rectally if he underwent an ERCP. The Second Defendant says (R/26/p. 215-216),

“23. Whilst in the clinic on 14 June with the Claimant, I explained my recommendation that a ERCP procedure was appropriate to remove the stones if the MRCP confirmed the presence of stones in the common bile duct.

24. I discussed the procedure in detail with the Claimant and talked through the risks of the procedure, including the 3% risk of developing pancreatitis. The Claimant then had some time to consider the procedure before signing a consent form which was carried out on the day of the surgery.”

66. In cross-examination, the Second Defendant said that he did not at this consultation advise the Claimant that he was going to receive a Diclofenac suppository rectally (transcript 16.03.26, p. 90).
67. I conclude that it is common ground that the Claimant was not advised by the Second Defendant at the consultation on 14 June 2019 that if he underwent an ERCP, Diclofenac would be administered rectally.

Should the Claimant have been advised as part of the consenting process on 16 July 2019 that Diclofenac would be administered rectally?

68. The Claimant was consistent throughout that he was not advised that Diclofenac would be administered rectally. In his supplementary statement, dated 16 September 2025, the Claimant says (R/25/p. 209),

“6. On the day of the procedure, I think that Dr Reffitt came to see me in my private room before I was taken down to the pre-theatre room. I can recall Dr Reffitt going through a form and mentioning some risks attached to the procedure. At no point did he mention a rectal suppository, or guarding against the risk of pancreatitis.

...

8. To clarify, at no time prior to, during or following the ERCP procedure did any of the nurses or Dr Reffitt have any discussion with me regarding the insertion of a rectal suppository and the risks or benefits associated with this.

9. As set out in my initial statement, I recall being in two separate rooms - a smaller room which I was wheeled to in a trolley, and the theatre room which I was then taken to. In neither of these rooms was a discussion had regarding a rectal procedure.

10. Whilst in the smaller pre-theatre room, I can recall being given a spray down my throat which had a kind of banana flavour to it. ... Following the throat spray, I was taken into the theatre room. The use of a suppository was not discussed with me by either Dr Reffitt or any of the nursing staff in either of these rooms. Again, I am sure that I would remember being told that I was going to be given a rectal suppository.”

69. The First Defendant says in its Part 18 response (R/14/p. 92),

“It is normal practice for a nurse administering medication per rectum to notify the patient before administration that the drug will be placed in the rectum, after the Fentanyl and Midazolam had been given.”

70. Mr Deppeler, the First Defendant’s Endoscopy Manager, agreed in cross examination that the Claimant would have to be advised that Diclofenac was going to be administered rectally prior to sedatives being given (transcript 16.03.26, p. 43-44):

“MR DUFFY: In terms of the administration of diclofenac, a nurse would notify the patient in advance that a suppository was going to be placed in the rectum. That's right, isn't it?

MR DEPPELER: They would indicate that it was going to be placed, yes.

MR DUFFY: Because it's an internal examination, isn't it?

MR DEPPELER: Correct.”

71. The Second Defendant deals with consent on the day of the procedure at paragraph 31 of his witness statement. He does not say that he notified the Claimant that an NSAID would be administered rectally. He says (R/26/p. 216),

“31. Prior to the procedure and exhibited at ‘DR2’ is a copy of the consent form that the Claimant signed. I went through the procedure with him prior to surgery and set out the risks involved. I have noted these as ‘bleeding of 1% with the sphincterotomy and perforation of 1%’. I have also outlined a risk of pancreatitis at 3%.”

72. On 16 July 2019 the Second Defendant completed the consent form (core bundle/5/p. 779-780). The Second Defendant did not tick the box “The procedure will involve rectal administration of drugs”. Nor are the boxes stating that the procedure will involve general and/or regional anaesthesia or sedation ticked. The Second Defendant has signed the consent form immediately beneath the section “rectal administration of drugs”; indeed, his signature overlaps the option “rectal administration of drugs”.
73. In cross-examination, the Second Defendant said (transcript 16.03.26, p. 94-95),
- MR DUFFY: There was no discussion, was there, that he was going to get a diclofenac suppository, was there?
- SECOND DEFENDANT: There was absolutely discussion. That was where -- I mean, we're very creatures of habit, consultants, and you go through a routine, and at that point we go through the risks of the procedure, the risk of bleeding, risk of perforation, the risk of pancreatitis, and then what will happen in the procedure room, that a cannula will be -- on to a bed, where your pulse, blood pressure, oxygenation is measured, that, 'You'll have a cannula put in and you'll be given sedation with fentanyl, which is a pain relief, and midazolam, you'll have throat spray administered', and at that point I would then mention the rectal diclofenac. It's what I do sort of day in/day out and always follow the same pattern.”
74. In cross-examination, the Second Defendant admitted that the Claimant should be told in advance that he was going to have a rectal examination and that Diclofenac would be inserted (transcript 16.03.26, p. 101-102):
- “MR DUFFY: I think you accept, then, that a patient should be told in advance that they're going to have a rectal examination and that diclofenac is going to be inserted?
- SECOND DEFENDANT: I totally agree that they should be told in advance, yes.”
75. In his report, dated September 2025, Professor Gilmore says (R/31/p. 257, lines 168-172),
- “A rectal procedure constitutes an internal examination, and if the court finds this was not explained, it would constitute substandard practice. I note that the intention to administer a drug rectally was not ticked on the consent form signed by Mr Alexander.”
76. In his expert report, dated 31 October 2025, Dr Anderson, the Second Defendant's expert Consultant Gastroenterologist, discusses the consent form in his opinion section at paragraph 4 (R/36/p. 428):

i) He makes no criticism of the Second Defendant's failure to complete in the consent form the sections related to the rectal administration of drugs, anaesthesia and sedation.

ii) He says,

"I would expect the consent process to discuss the risks of the procedure and the type of sedation / anaesthesia but I would not expect any discussion about specific medication including the use of a diclofenac suppository."

77. I note that when Dr Anderson came to make the joint statement with Professor Gilmore and Dr Woodward, he changed his position and agreed that:

i) The Second Defendant should have completed in the consent form the sections related to the rectal administration of drugs, anaesthesia and sedation.

ii) The Claimant should have been advised that Diclofenac would be administered rectally prior to its administration.

78. In the joint statement of the experts in Gastroenterology, dated 5 January 2026, it is said (R/40/p. 522),

"2.13 m) Should the Second Defendant have completed the sections relation to anaesthesia, sedation and rectal administration of drugs? ... All experts agreed that the appropriate boxes should have been completed on the consent form.

2.14 n) If Diclofenac was to be administered rectally, should the Claimant have been advised of this prior to administration by nursing staff? All experts agreed that such should be communicated to the patient prior to administration.

...

3.02 They agreed that ... the patient undergoing ERCP should be informed of the use of rectal NSAID prior to administration."

79. Further, evidence of Dr Anderson's change of position could be seen in cross-examination, Dr Anderson was asked (transcript 18.03.26, p. 11-12),

"MR DUFFY: I think we've seen reference on 224 to the box which isn't ticked for rectal administration of drugs and we heard evidence from Dr Reffitt about that. It is a prompt, isn't it, for the doctor to discuss the rectal administration of drugs when he's completing this form?

DR ANDERSON: They'd discuss the route of administration and types of drugs being given, yes.

MR DUFFY: Yes. And so, if there is such a prompt on the consent form, that discussion should have taken place when this form was being signed?

DR ANDERSON: The discussion should take place and it should be -- the appropriate ticks applied to the relevant boxes because in this case local anaesthesia, sedation and rectal administration should all be ticked."

Finding

80. I find that all the lay and expert evidence is in agreement that the Claimant should have been informed as part of the consenting process that Diclofenac would be administered rectally.
81. I am concerned that Dr Anderson thought it appropriate to say in his report that he would not expect any discussion about the use of a Diclofenac suppository. I find that this position is untenable and would constitute substandard and negligent practice. I find that Dr Anderson's evidence on this point diminishes his credibility as an independent expert and results in my being able to place less weight on his evidence. I also note that Dr Anderson did not comment on the fact that the Second Defendant did not complete the sections in the consent form relating to anaesthesia and sedation.

Would the Claimant have been able to recall being advised that Diclofenac would be administered rectally?

Evidence

82. The Claimant was consistent throughout that he was not advised that Diclofenac would be administered rectally, and he remembered being given a throat spray. In his supplementary statement, dated 16 September 2025, the Claimant says (R/25/p. 209),

"10. Whilst in the smaller pre-theatre room, I can recall being given a spray down my throat which had a kind of banana flavour to it. I am pretty sure that I was lying on my back at this point. I do not recall being moved onto my side at any point.

Following the throat spray, I was taken into the theatre room. The use of a suppository was not discussed with me by either Dr Reffitt or any of the nursing staff in either of these rooms. Again, I am sure that I would remember being told that I was going to be given a rectal suppository."

83. In cross-examination, the Claimant was asked by Mr Perfect (transcript 16.03.26, p. 27)

MR PERFECT: It's just about the sequencing in terms of what happens because your understanding is first of all that you were given I think a throat spray; is that right?

CLAIMANT. Yes, I certainly recall that.

84. Professor Gilmore said in cross-examination (transcript 17.03.26, p. 5),

“It's unlikely that people would forget things that happened before they received the injection [for sedation].”

85. The Consultant Gastroenterologists for the First and Second Defendants, Dr Woodward and Dr Anderson, both sought to argue that the Claimant would not remember being advised that Diclofenac would be administered rectally and would not remember the administration of Diclofenac because the suppository would be administered immediately after the administration of sedative drugs:

- i) Dr Woodward, the First Defendant's Gastroenterologist, says in his report (R/35/p. 405),

“6.11 ... I note in this regard that it is not uncommon to give the suppository right at the beginning of the procedure or immediately after the administration of intravenous sedative drugs. As a result, he may not have been aware of the administration of the suppository.”

- ii) Dr Anderson says in the Consultant Gastroenterologists' joint statement (R/40/p. 522),

“... MA ... considered that it might be that the sedation had already taken effect by the time that rectal administration was considered and that under these circumstances, if heavily sedated, it might be appropriate to administer without the patient being explicitly roused and informed of such. This would be preferable to the risk of not administering it in such a circumstance. IG and JW were broadly in agreement.”

86. The Second Defendant also sought to argue that Claimant would not remember being advised that Diclofenac would be administered rectally and would not remember the administration of Diclofenac, because this would have been done after he had received sedatives. The Second Defendant said in cross-examination (transcript 16.03.26, p. 101),

“SECOND DEFENDANT: ... and he's consented before the procedure, so it's likely to be 15/20 minutes before the procedure.

MR DUFFY: All right. So his memory was wiped, was it, for all that time? That's your evidence to the court?

SECOND DEFENDANT: It's not evidence. It's what happens with midazolam. It very often affects memory, the conversation that occurs. That's not me saying that.”

Finding

87. I find the Defendants' argument that the Claimant would not remember being informed that Diclofenac would be administered rectally or remember Diclofenac being administered rectally is fundamentally flawed on two bases.

88. Firstly, both Dr Anderson and Dr Woodward agreed in cross examination that if the Claimant could remember the Xylocaine throat spray being administered, he would remember being told that Diclofenac was going to be administered rectally:

i) Dr Woodward said in cross-examination (transcript 17.03.26, p. 85):

“Mr Duffy: If he remembers the throat spray, the sedation hasn't affected his memory before the throat spray on the balance of probabilities?

Dr Woodward: Then, yes, clearly the sedation hasn't affected his memory of the throat spray, if he recalls that.”

ii) Dr Anderson was asked in cross examination (transcript 18.03.26, p. 14),

“In relation to how far back it [sedation] might impede memory, if the claimant can remember the throat spray and the court accepts that evidence, he can probably remember before the throat spray; do you accept that?”

Dr Anderson replied, “I think that's probably correct.”

89. Secondly, the Defendants’ argument proceeds on the basis that the Claimant would have been consented for the rectal administration of Diclofenac while under the effect of sedation, and I find that this would have constituted substandard and negligent practice. I find that the evidence of the First Defendant and the Second Defendant shows overwhelmingly that the advice that Diclofenac would be administered rectally should have been given before the Claimant was sedated:

i) Mr Deppeler said in cross-examination (transcript 16.03.26, p. 43-44),

“MR DUFFY: And so the patient would need to be told in advance that it was going to be done --

MR DEPPELER: Yes.

MR DUFFY: -- irrespective of sedation?

MR DEPPELER: Yes.

MR DUFFY: And that discussion has to happen before sedation, doesn't it?

MR DEPPELER: Yes.

MR DUFFY: You can't sedate somebody and then tell them they're going to have an internal examination?

MR DEPPELER: Yes.”

ii) The Second Defendant said in cross-examination (transcript 16.03.26, p. 101-102):

“MR DUFFY: And that's before they're sedated for obvious reasons?

SECOND DEFENDANT: Yes.

MR DUFFY: And before they're lying down on the trolley getting the xylocaine spray, for instance?

SECOND DEFENDANT: Yes, it happens as part of the consent process.”

90. For the aforementioned reasons, I reject the Defendants’ contention that the Claimant would not have been able to remember whether he was advised that Diclofenac was administered rectally.

Was the Claimant advised on the day of the procedure that Diclofenac would be administered rectally?

Evidence

91. It is common ground that the Claimant was not advised at his consultation with the Second Defendant on 14 June 2019 that if he underwent an ERCP, he would be given a non-steroidal anti-inflammatory rectally. See paragraphs 64-67 above.
92. The Claimant’s evidence is that he was not told by the Second Defendant or by the First Defendant’s nurses that Diclofenac was going to be administered rectally. He recalls being given a banana-flavoured spray and it is common ground that if he remembered that, he would remember being consented for the rectal administration of Diclofenac. I repeat paragraph 68 above.
93. In cross-examination, there was the following exchange between Mr Cox and the Claimant (transcript 16.03.26, p. 25),

“MR COX: You say that the idea of a suppository, not something particularly pleasant -- and you make the point that you think you would remember if something like that had been done to you as part of the procedure.

CLAIMANT: Well, I mean, I certainly would remember if it was prior to me being sedated”.

94. Nurse Mondido and Nurse Ferrari both say in their witness statements that they have no recollection of the procedure on 16 July 2019 (R/28/p. 234 and R/29/p. 246 respectively).

Finding

95. Throughout the proceedings I found the Claimant to be a reliable, understated and truthful witness. The Claimant is stoical and has not in any way embellished or exaggerated his evidence.

96. The Claimant's evidence has been consistent throughout. He says in his witness statement of 6 November 2024 at paragraph 9 (R/23/p. 190) that he does not recall a rectal suppository being inserted. At paragraphs 6, 8, 9 and 10 of his supplementary witness statement, dated 16 September 2025 (see paragraph 68 above) he says that on the day of the ERCP neither the Second Defendant nor any of the nurses advised him that a rectal suppository would be administered.
97. I found the Second Defendant to be an unreliable witness. His evidence in Court was radically different to his witness statement. In his witness statement the Second Defendant does not say that he or the nurses informed the Claimant that an NSAID would be administered rectally. However, in cross examination, he was adamant that (transcript 16.03.26, p. 94-95), "There was absolutely discussion" with the Claimant. What was conspicuous was that the Second Defendant's evidence was all based on his standard practice and not his recollection of the Claimant and the ERCP on 16 July 2019. As he said, "We're very creatures of habit, consultants, and you go through a routine ... it's what I do day in/day out and always follow the same pattern".
98. I reject the Second Defendant's evidence at trial that he consented the Claimant for the administration of Diclofenac for the following reasons.
99. It is contradicted by the contemporaneous documentary evidence. On the Consent Form, the Second Defendant did not tick the box for rectal administration of drugs. This box was plain to see and next to the place for the Second Defendant's signature; indeed, the Second Defendant's signature overlaps the box for the rectal administration of drugs.
100. In the Consultant Gastroenterologists' joint statement, they agree at paragraph 3.02 (R/40/p. 527), "All relevant parts of the consent form should be completed".
101. If the Second Defendant had consented the Claimant for the rectal administration of Diclofenac, it is highly likely that Diclofenac would have been added to the Drug Prescription and Administration Chart and the Second Defendant would have countersigned it, as he countersigned the administration of other drugs on this chart.
102. I have found the Claimant to be a truthful and reliable witness.
103. I find the Second Defendant to be not a credible witness. In cross-examination, the Second Defendant sought to give two contradictory explanations for his failure to state on the consent form that he had advised the Claimant that Diclofenac, an NSAID, would be administered to him rectally. At first, the Second Defendant blamed a lack of familiarity with the consent form (transcript 16.03.26, p. 95).

MR DUFFY: ... Do you always follow the same pattern of not completing the consent form correctly?

SECOND DEFENDANT: No, that was an error, and it was because we used procedure-specific consent forms at Lewisham Hospital and at King's, and we were using them at London Bridge until around that time we were informed that we could no longer use the procedure-specific consent form and that we'd need to move to a generic form which is used for all operations

and theatre procedures, and my mistake was I was unfamiliar with the form and I missed the -- I didn't tick -- I agree I didn't tick 'diclofenac', but I didn't tick the 'sedation' box either. I just missed that and it was an error on my behalf."

I find this explanation not credible because the consent form is very simple and the Second Defendant's signature goes through the box, "This procedure will involve ... rectal administration of drugs", which is not ticked.

104. Secondly, the Second Defendant then sought to blame the consent form. He said (transcript 16.03.26, p. 99),

"It's a rubbish consent form because it's generic because it's used for any procedure, so we have to really explain verbally what's happening."

105. However, I find that this second explanation lacks credibility for the same reason as stated at paragraph 103 above.

106. For the aforementioned reasons, I find on the balance of probabilities that the Claimant was not advised by the Second Defendant as part of the consenting process on 16 July 2019 that an NSAID, Diclofenac, would be administered rectally if he underwent an ERCP.

107. I accept the Claimant's evidence that the nurses did not advise him that they were going to administer Diclofenac. Nurse Mondido and Nurse Ferrari do not say that they advised him of this; they both say they have no recollection of the procedure on 16 July 2019.

Where should a prescription for Diclofenac have been recorded in the medical records?

108. The Second Defendant says in his witness statement at paragraph 36 (R/26/p. 217),

"I accept that this chart [Drug Prescription and Administration Chart] does not reference Diclofenac. There is however no space for this to be added to the records."

109. I find this statement misleading because the Second Defendant and the Consultant Gastroenterologists all agree that another page should have been added to the Drug Prescription and Administration Chart or Diclofenac should have been written on the Drug Prescription and Administration Chart:

- i) In cross-examination the Second Defendant accepted (transcript 16.03.26, p. 120),

"The mistake at the end was that it should have been -- because on this -- another -- there should have been another blank form where that -- that would be attached to this form that had the diclofenac on. It's not this form; it's another form that's empty and not prefilled that should have been manually filled in."

- ii) In the Consultant Gastroenterologists' joint statement, the experts say (R/40/p. 520),

“2.04 d) Where should prescription of the Diclofenac have been recorded in the records? All three experts agreed that the diclofenac should have been prescribed on the prescription chart.”

- iii) The Consultant Gastroenterologists say under the heading “Summary of points of agreement and disagreement” (R/40/p. 527),

“They agreed that diclofenac should be prescribed in a prescription chart on which administration should be noted.”

110. However, the First Defendant’s Endoscopy Manager, Mr Deppeler, said in cross-examination (transcript 16.03.26, p. 41,) that the prescription for Diclofenac should have been included in the ward drug chart or, as it is sometimes called, the short stay drug chart:

“MR DUFFY: Is there an option for a surgeon to say, ‘I want a different drug pre-populated on this sheet’, or does that have to be dealt with by other means?

MR DEPPELER: It’s usually by other means, but if there was an additional drug, it is written on the short stay drug chart.”

111. I find that it is troubling that there is a difference of opinion between the First Defendant’s Endoscopy Manager, the Second Defendant and the three expert Consultant Gastroenterologists as to whether Diclofenac should be recorded in the Drug Prescription and Administration Chart or the short stay drug chart. In this case, Diclofenac was not recorded in either the Drug Prescription and Administration Chart (R/26/p. 226) or the short stay drug chart (core bundle/10/p. 2688).
112. I find on the balance of probabilities that a prescription for Diclofenac should have been recorded in the Drug Prescription and Administration Chart.

Evidence of Mr Deppeler on failure to record Diclofenac in hospital medical records

113. Mr Deppeler seeks to characterise the failure to record Diclofenac in:

- i) The Drug Prescription and Administration Chart or the Short Stay Drug Chart
- ii) The Medication Discharge Summary

as a “minor recording omission” (R/27/p. 229).

114. I reject the evidence of Mr Deppeler that the failure to record Diclofenac in these three documents can just be characterised as a “minor recording omission”. As Professor Gilmore says in his report at paragraph 2.5 (R/31/p. 258), “Failing to do so is not a ‘minor clerical error’ ... but ignoring a basic tenet of safe prescribing”.

Must a written prescription be given to administer a prescription drug in hospital?

Human Medicines Regulations 2012/1916

115. The supply of prescription medications is governed by Regulation 214 of the Human Medicines Regulations 2012/1916, which provides (authorities bundle/9/p. 301),

“Sale or supply of prescription only medicines

214.— (1) A person may not sell or supply a prescription only medicine except in accordance with a prescription given by an appropriate practitioner...

... (3) The following are appropriate practitioners in relation to any prescription only medicine—

(a) a doctor

116. In hospital the term “in accordance with a prescription” is governed by Regulation 227, which provides (authorities bundle/9/p. 305-306),

Exemption for sale or supply in hospitals

227.— (1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine—

(a) in the course of the business of a hospital; and

(b) for the purpose of being administered (in the hospital or elsewhere) to a particular person in accordance with directions that meet the conditions in paragraph (2).

(2) Those conditions are that the directions—

(a) are in writing;

(b) relate to the particular person to whom the prescription only medicine is to be administered; and

(c) are given by a person who is an appropriate practitioner in relation to that prescription only medicine. (my emphasis)

Evidence

117. In the Defence of the First Defendant, dated 22 January 2024, it is said (R/9/p. 61),

“10.3 By convention and for obvious reasons, all prescriptions of medication must be recorded in writing, as must their administration.”

118. This was changed in the amended Defence of the First Defendant, dated 18 March 2025, as follows (R/12/p. 81):

“10.3 By convention and for obvious reasons, all prescriptions of medication ~~must~~ should be recorded in writing, as ~~must~~ should their administration.”

119. In his expert report, dated September 2025, Professor Gilmore says (R/31/p. 258, lines 209-216),

“Despite the nurses’ witness statements that if it had been asked for it would have been given, no nurse would or should give a drug to a patient without it being prescribed on the patient’s named prescription chart and without signing that it was administered at a particular date and time. Failing to do so is not a ‘minor clerical error’, as stated in one witness statement from the nursing staff but ignoring a basic tenet of safe prescribing. I conclude that it was Dr Reffitt’s intention to prescribe diclofenac and, if it was neither prescribed nor administered, this constitutes a breach of duty.”

120. The Second Defendant says in his witness statement, dated 4 December 2024 (R/26/p. 218):

“39 b. ... It is routine practice to sign for [...] all medication at the end of the procedure when we know the exact doses that have been required during ERCP.”

121. The Second Defendant said in cross-examination (transcript 16.03.26, p. 119),

“MR DUFFY: There's an opportunity then, isn't there, to say, 'Well, I need to give a prescription of diclofenac in writing'? That's right, isn't it?

SECOND DEFENDANT: We don't give it in advance. We don't -- we give it orally and then we sign for it at the end of the procedure because you don't, until the end of the procedure, know what medications have been given.”

122. The Second Defendant did not even acknowledge in his witness statement or his oral evidence the existence of Regulation 227 of the Human Medicines Regulations 2012/1916, let alone acknowledge that it should be complied with. This reflects detrimentally on his credibility.

123. In his expert report, Dr Woodward says (R/35/p. 406), “In my experience it was common for the rectal NSAIDs to be prescribed ‘on word of mouth’ by the endoscopist”. Mr Deppeler makes a similar comment in his witness statement, dated 10 March 2025 (R/27/p. 229),

“8. ... It is commonplace for a verbal direction to be given by a surgeon to nursing staff to administer Diclofenac as a rectal suppository prior to an ERCP procedure”

124. Neither Dr Woodward nor Mr Deppeler acknowledge that this is in breach of Regulation 227 of the Human Medicines Regulations 2012/1916.
125. There is no acknowledgment by Mr Deppeler in his witness statement that pursuant to Regulation 227 of the Human Medicines Regulations 2012/1916, it was a legal requirement that the directions for a prescription drug in hospital be in writing. In cross-examination, Mr Deppeler admitted for the first time that it was a legal requirement that medication administered before the procedure must be recorded in writing (transcript 16.03.26, p. 39):

“MR DUFFY: I mean, it’s a legal requirement, isn’t it, that administration take place after a direction in writing?

MR DEPPELER: Yes.

MR DUFFY: So there has to be something in writing first before you can administer a medication?

MR DEPPELER: Not always during a procedure because you’re in the middle of a procedure so you could be asked to be given a drug.

JUDGE ROBERTS: But if it was given before the procedure, wouldn’t the law be that it’s in writing first?

MR DEPPELER: Yes.”

126. Nurse Mondido and Nurse Ferrari both say in their witness statements that it is usual practice for verbal instructions to be given by the surgeon for the administration of Diclofenac suppositories in an ERCP procedure (R/28/p. 234 and R/29/p. 240 respectively).

Finding as to whether written instruction must be given to administer a prescription drug in hospital

127. I find that in a hospital, prescriptions must be in writing not by convention, as the First Defendant says at paragraph 3 of the amended Defence (R/12/p. 81), but by reason of Regulation 227 of the Human Medicines Regulations 2012/1916.
128. Neither Defendant in their statements of case, witness statements or expert reports displayed any awareness of Regulation 227 of the Human Medicines Regulations 2012/1916.
129. There is an example of a written prescription being required in the present case. When it was discovered by RMO Clark-Morgan an hour after the procedure had concluded that the Claimant had not been given the antibiotic Ciprofloxacin, RMO Clark-Morgan called the Second Defendant and did not simply give the Claimant the dose of Ciprofloxacin but also made a written prescription in the Short Stay Drug Chart (core bundle/10/p. 2688).
130. I find that the Drug Prescription and Administration Chart (R/26/p. 226) is the record of medication used by the Hospital. It records all prescription medicines prescribed and

administered. It records the time of administration, the dose and the method of administration, and is signed by the nurse and countersigned by the consultant. It is the record which is relied upon by the nursing staff for medication administration.

131. In the joint statement the Consultant Gastroenterologists say (R/40/p. 520),

“All three experts agreed that the diclofenac should have been prescribed on the prescription chart”.

132. Despite saying in the Consultant Gastroenterologists’ joint statement that Diclofenac should have been prescribed on a prescription chart, in his evidence Dr Woodward sought to walk this admission back and to reduce a legal requirement to an ideal to be aspired to. He said in his evidence (transcript 17.03.26, p. 83),

“So ideally a prescription should be written out beforehand and then signed after it’s administered.”

133. I find that the need for a prescription to be in writing before a drug is administered is not an ideal, but a legal requirement. Dr Woodward’s attempt to defend the failure to provide a written prescription reflects detrimentally on his credibility.

134. I do not accept the assertion of Dr Woodward or the First and Second Defendant’s witnesses that it is common for rectal NSAIDs to be prescribed by word of mouth for the following reasons:

- i) Dr Woodward agreed in the joint statement (R/40/p. 520), “All three experts agreed that the Diclofenac should have been prescribed on the prescription chart”. Dr Woodward did not say in the joint statement that it was common for rectal NSAIDs to be prescribed by word of mouth.
- ii) The joint statement chimes with the evidence of Professor Gilmore in his report that (R/31/p. 258), “no nurse would or should give a drug to a patient without it being prescribed on the patient’s named prescription chart”.
- iii) The Second Defendant accepted eventually in cross-examination that a nurse would need a written direction in order to administer medication (transcript 16.03.26, p. 120-121):

MR DUFFY: Yes, and it should have been done in advance of being administered as well, shouldn't it?

SECOND DEFENDANT: Nearly all medications are signed after they've been administered during the procedures.

MR DUFFY: For a nurse, a nurse needs a written direction in hospital in order to administer medication, so that needs to come before it's administered. You would accept the sense of that, wouldn't you?

SECOND DEFENDANT: Yes.

- iv) The First Defendant's Endoscopy Manager, Mr Deppeler, says in his witness statement (R/27/p. 228),

"7. In 2019, and indeed today, the usual protocol would be for the clinical staff to document the medication given to a patient during a procedure by completing the drug administration chart on the electronic Meditech system. The treating surgeon would also complete the operation record."

- v) Far from saying that it was common for rectal NSAIDs to be prescribed on word of mouth, Mr Deppeler says in his witness statement at paragraph 8 (R/27/p. 228),

"I can offer no explanation for the fact the Diclofenac was not recorded on the drug administration chart at the time of the Claimant's procedure on 16 July 2019."

135. Mr Deppeler and the Second Defendant both sought to suggest that a prescription could not be given because it was not known until the end of the procedure that Diclofenac would be given:

- i) Mr Deppeler said (transcript 16.03.26, p. 39):

"MR DUFFY: So there has to be something in writing first before you can administer a medication?"

MR DEPPELER: Not always during a procedure because you're in the middle of a procedure so you could be asked to be given a drug.

JUDGE ROBERTS: But if it was given before the procedure wouldn't the law be that it's in writing first?

MR DEPPELER: Yes"

- ii) The Second Defendant (transcript 16.03.26, p. 119),

"... We don't -- we give it orally and then we sign for it at the end of the procedure because you don't, until the end of the procedure, know what medications have been given."

136. I reject the submission of Mr Deppeler and the Second Defendant because it was known from the very outset that Diclofenac would be administered pre-procedure:

- i) In the First Defendant's Part 18 response it is said (R/14/p. 93),

"Diclofenac would have been administered in theatre before the procedure".

- ii) In the witness statement of the Second Defendant he says (R/26/p. 217,

“38. It is my routine practice to ask for Diclofenac to be prescribed in all cases of ERCP that I perform at the start of the procedure.”

137. I find that I can place very little weight on the evidence of Nurse Ferrari on this point. Nurse Ferrari did not attend the trial and so her evidence has not been tested by cross-examination.

138. Regarding Nurse Mondido, I would make the following points:

- i) In her statement, Nurse Mondido says at paragraph 4 (R/28/p. 233), “This statement has been drafted by DAC Beachcroft LLP”. The statement has been written by the First Defendant’s solicitors. It reads more as a list of submissions than a witness statement. Nurse Mondido says in her witness statement at paragraph 6 (R/28/p. 234), “I have no recollection of the procedure on 16 July 2019”. The statement frequently wrongly strays into argument. For example, the whole of paragraph 8 is argument and is inappropriate (R/28/p. 234):

“Put simply, my understanding of the records that I have interpreted for the Claimant are that the record of Diclofenac as stated by Dr Reffitt constitutes evidence that the medication was given as directed in relation to this patient. To me, it is inconceivable that a Consultant would request that nursing staff administer the medication and then they fail to do so. Furthermore, Dr Reffitt states in his Defence that he has a specific recollection of the medication being given. I refer again to my comment above that it is my usual practice to query with a Consultant whether they intend to give a patient Diclofenac during an ERCP procedure if such a request has not been made.”

- ii) Nurse Mondido’s evidence is contradictory. At paragraph 7 she says (R/28/p. 234), “It is usual practice to take verbal orders from a Consultant when undertaking an ERCP procedure”. However, at paragraph 9 she says, “A Consultant will enter the medication onto the drug chart and the nursing staff will countersign it to confirm that it has been given”.

Was a written prescription for Diclofenac given by the Second Defendant?

139. The three Consultant Gastroenterologists agree that a written prescription for Diclofenac should have been made in the Drug Prescription and Administration Chart. There was no written prescription in the Drug Prescription and Administration Chart.

140. The only document in which Diclofenac is recorded is the Second Defendant’s ERCP report, which he wrote after the procedure had been completed. Nurse Mondido said that this could be considered a written prescription for Diclofenac. In her witness statement, she says (R/28/p. 234),

“From my recollection, the ERCP report would then be used as a record of medication.”

141. I am unable to accept Nurse Mondido's evidence because she accepted this was wrong, as did Mr Deppeler:

i) In cross-examination Nurse Mondido accepted that the ERCP report is not a nursing record of medication (transcript 16.03.26, p. 71-72):

"MR DUFFY: You would accept, wouldn't you, that when the consultant makes the ERCP report, that's not a nursing record, is it?

NURSE MONDIDO: No.

MR DUFFY: That's for the consultant to complete?

NURSE MONDIDO: Yes."

ii) Mr Deppeler said in cross-examination (transcript 16.03.26, p. 38),

"Q. But it's [the ERCP report] Dr Reffitt's document, isn't it, not a nursing document?

A. It's not, but we check it as part of our time out at the end of a procedure.

Q. So it shouldn't be relied upon by nursing staff for medication administration, should it?

A. No."

142. I accept the evidence of Professor Gilmore, who says in his report at paragraph 2.5 (R/31/p. 258),

"However, that ERCP report does not constitute a prescription and cannot be accepted as one."

not least because it is agreed by all three Consultant Gastroenterologists.

143. I find on the balance of probabilities that a written prescription was not given by the Second Defendant to the First Defendant's nurses to administer Diclofenac.

Did the First Defendant's nurses input premedication into Second Defendant's ERCP report?

Evidence

144. The evidence of the Second Defendant in his witness statement was that he typed the ERCP report immediately after the surgery took place (R/26/p. 216):

"27. Exhibited hereto and marked "DR1" [the ERCP report] is a copy of my operation note **following the procedure** on 16 July 2019. In accordance with my usual practice, **I typed this**

operation note immediately after the surgery took place.”
(my emphasis)

145. The Second Defendant does not say in his witness statement that the ERCP report was a collaborative exercise with the nurses and that they inputted the pre-medication.
146. The first time that the Second Defendant said that his ERCP report was a collaborative exercise with the nurses and that they inputted the premedication drugs in his ERCP report was on the first day of trial in cross-examination (transcript 16.03.26, p. 110-112),

“MR DUFFY: Right. But the nurses don't remember either, do they, so that doesn't help anybody? We're talking about your direct recollection.

SECOND DEFENDANT: I only know that if I -- I've written in my report, which involves the nurses, that I gave diclofenac. That report [the ERCP report] is not me just writing it -- putting it in at the top. That report is filled in by a nurse, who sat on a chair in front of the computer, and she is putting down the drugs and then I go at the end of the procedure, look at that page and confirm them. So it's a conversation between me and the nurses. Why on earth would I have written that I've given diclofenac if I hadn't given it?

...

MR DUFFY: Let's take that in stages. We're talking about the ERCP report.

SECOND DEFENDANT: Yes.

MR DUFFY: Are we?

SECOND DEFENDANT: We're talking about the report. That's how it's generated. It's generated by a nurse putting in the medication and me -- in communication with me.

...

MR DUFFY: And your position today is that the section 'Pre-medication', with the four drugs listed in it, that wasn't entered by you, that was entered by Nurse --

SECOND DEFENDANT: That is entered by a team, so that is not entered by one person. That is entered by -- recorded by the nurse during the procedure and confirmed by me at the end of it. So when we said, 'Oh, the procedure is written after ...' -- 'The form is written after the procedure', it's filled in as you go along. You go through stages -- you go on to the next page, you go through stages. One of the pages has the medication, and that is done by the nurse, and then, when I'm confirming the report, I

confirm what's written, I check with the nurses, just as they've checked with me during the procedure, what's been administered, I check with them again as I'm writing the report. The patient isn't allowed to leave the room, none of the nurses leave the room, until we're happy the report has been written. As happens on a weekly basis, the nurses are meticulous about getting the reports correct, and if they notice that something is wrong with the medication, they'll point it out to you and you redo the report."

147. In re-examination by Mr Perfect, the Second Defendant said (transcript 16.03.26, p. 151-253),

So the person who is Meryl, who's the third person in the room, is recording what's happening during the procedure, and one of the things is, as you give the fentanyl, they say, 'How much did you give?', 'I gave 50 micrograms' -- in this case I gave 100 because it's an ERCP, it's quite a technical procedure; 'How much midazolam did you give?'; sometimes you give 2 at the beginning, then you wait and see how sedated the patient is -- obviously, you're monitoring the oxygen saturations -- sometimes you give more, but every time you do it, it's recorded. It's recorded on the computer by the person in front of the computer.

So the conversation would be, 'Okay, what have you given?'; 'I've given 102. I'm actually giving another 2 now, so I would have given 104 of midazolam'. That person is recording on a tick-box page on the computer recording endoscopy system, which is not done by the consultant written at the end of procedure, it's recorded as the procedure goes on. At the end of the procedure it's the nurses who -- for example, they will record when the patient -- when the procedure stops, but at the end of the procedure -- and they're checking that any photos you take are being uploaded on to the reporting tool -- and then, at the end of the procedure, I, you know, put my ERCP scope down, I go and wash -- take my gloves off, take my apron off, wash my hands, take any protective radiation equipment off, and then I go and look at the report and I check -- the first thing I do is check -- and nobody had left the room at this point -- but I check the medication, that it's been administered, and you do just like the list said; you know, 'How much midazolam was given?', 'We gave 4'; 'How much fentanyl was given?', 'We gave 100 micrograms'; 'Did we give the rectal suppository?', 'Yes'. Then I go on to the next page of the report."

148. In his witness statement, dated 10 March 2025, Mr Deppeler says that the clinical staff and the Second Defendant completed the Drug Prescription and Administration Chart and the Second Defendant completed the ERCP report. He does not say that the nurses inputted the premedication in the Second Defendant's operation note (R/27/p. 228),

“7. In 2019, and indeed today, the usual protocol would be for the clinical staff to document the medication given to a patient during a procedure by completing the drug administration chart on the electronic Meditech system. The treating surgeon would also complete the operation record. I would have expected Dr Reffitt to complete the drug administration chart to include Diclofenac which in turn would be signed by the nursing staff to confirm that the medication has been given to the patient.”

149. The First Defendant’s Nurse Mondido said in her witness statement, dated 11 March 2025, that the Second Defendant completed the ERCP report immediately after the procedure and did not say that the premedication was inputted by the nurses (R/28/p. 234-235),

“9. ... That report [ERCP report] would have been completed by Dr Reffitt immediately after the procedure and therefore represents a contemporaneous record.”

Finding

150. I find that the Second Defendant’s evidence from the witness box that the medication in the ERCP report was inputted by the nurses before and during the ERCP and that there was a read out of the medication after the conclusion of the procedure, is contradicted by the evidence.
151. The Second Defendant’s evidence in his witness statement was very clear. He said that he typed his operation note immediately after the surgery took place. He did not say that the pre-medication was inputted by the nurses or that he copied this into his ERCP report. The Second Defendant had no convincing explanation for why the evidence which he gave in the witness box was not included in his witness statement if it was true.
152. Mr Deppeler’s evidence in his witness statement was that (R/27/p. 228 at paragraph 7), “The treating surgeon would also complete the operation record”. He did not say that the ERCP report is a collaborative exercise with the nursing staff or that the premedication in the ERCP report was copied in from the nurses’ input.
153. When Mr Duffy was opening the case, Mr Cox intervened to emphasise that the Second Defendant completed the operation note immediately after the conclusion of the operation (transcript 16.03.26, p. 8):

“My Lord, if I can be of assistance, Mr Deppeler, one of the second defendant's witnesses, expressly said at page 228 that an operating surgeon will invariably complete the operation notes immediately after the conclusion.”

Mr Cox did not say that the ERCP report was a collaborative exercise between the Second Defendant and the nurses, and that the Second Defendant used information inputted by the First Defendant’s nurses.

154. Nurse Mondido did not say that the completion of the ERCP report was written collaboratively by the Second Defendant and the nurses, but to the contrary it was for the Second Defendant to complete, and this was consistent with the Second Defendant's witness statement and the witness statement of Mr Deppeler.
155. If there had been the collaborative exercise with the nurses as to the prescription drugs used as the procedure went along and at the end of the procedure, as the Second Defendant now says, it is inconceivable that the nurses would not have included Diclofenac in the Drug Prescription and Administration Chart if it had been given.
156. Nurse Bouwer completed the sign out on the WHO Surgical Safety Checklist at 17:55. If, as the Second Defendant now says, there had been a read out loud of Diclofenac after the ERCP had been completed, it is inconceivable that when Nurse Bouwer completed and signed the Medication Discharge Summary six minutes later at 18:01, she would not have recorded Diclofenac.
157. The First Defendant has not disclosed any computer record completed by the nurses during the ERCP procedure.
158. For the aforementioned reasons, I find on the balance of probabilities that as stated by the Second Defendant in his witness statement and confirmed by Mr Deppeler and Nurse Mondido, the Second Defendant typed his ERCP report immediately after the surgery had taken place. I find that the Second Defendant's evidence at trial that the premedication in his ERCP report was inputted by the nurses was not credible and I reject it.

Did the Second Defendant give the First Defendant's nurses an oral instruction to administer Diclofenac?

159. In the Defence of the Second Defendant, it is said (R/10/p. 70),

“16. For the further avoidance of doubt the Second Defendant avers that his expectation was that the Claimant would be, and his recollection is that the Claimant was as a matter of fact, given Diclofenac 100mg rectally.”
160. The Second Defendant relies upon the fact that in his ERCP report (R/26/p. 221), Diclofenac (PR) 100mg is written under Premedication. The Second Defendant says in his witness statement at paragraph 34 (R/26/p. 217),

“My operation note confirms that I requested for 100mg Diclofenac to be administered rectally at the start of the ERCP procedure by the nurses”.
161. I find that the Second Defendant's witness statement contains no direct recollection of the events on 16 July 2019. He says at paragraph 20, “Mr Alexander's procedure was the only private ERCP procedure I carried out in 2019, which is why I am able to recall it” (R/26/p. 215). However, his account is given from stating his usual practice, referring to his ERCP report and commenting on documents. He refers at paragraphs 27-29 (p. 216) to his operation note. At paragraph 34 he says, “It is my usual practice to always prescribe Diclofenac either before or during a ERCP procedure in all cases

in order to reduce the risk of post-procedure pancreatitis” (R/26/p. 217). At paragraph 36 he says, “in line with my usual practice I always prescribe Diclofenac and recall instructing the nurses to administer this.” However, at paragraph 39a (R/26/p. 218) he says, “My operation note confirms that I prescribed and asked for 100mg of Diclofenac to be administered rectally at the time of the procedure and I have no reason to think I did not prescribe it on this occasion”. At paragraph 39b he says, “It is routine practice to sign for [...] all medication at the end of the procedure when we know the exact doses that have been required during ERCP” (R/26/p. 218).

162. In cross-examination, the Second Defendant said that his witness statement was a full and complete recollection of events (transcript 16.03.26, p. 96). However, as will be seen below, in cross-examination his recollection grew, over 6½ years after the index event, and he gave an increasingly detailed account of the instruction and administration of Diclofenac. He could even remember conversation with Nurse Bouwer, which he had never mentioned before.

163. The Second Defendant said (transcript 16.03.26, p. 105-106),

“SECOND DEFENDANT: I remember asking for it to be administered to Meryl Bouwer and I remember having a conversation, she went, ‘Yes’ and ‘Absolutely’. So everything --

JUDGE ROBERTS: ‘Yes, absolutely’, you actually saw it administered?

SECOND DEFENDANT: I saw her getting the medication. The part that I will say I’m --

JUDGE ROBERTS: Sorry, you saw her get the medication?

SECOND DEFENDANT: I saw her get the medication.

JUDGE ROBERTS: And where did she get that from?

SECOND DEFENDANT: They have the medication ready on the side of the -- on the --

JUDGE ROBERTS: You saw her get that?

SECOND DEFENDANT: The medication -- we have a sign-in at the beginning, we talk about what’s going to happen, I asked for rectal diclofenac to be given, and there’s a box with the rectal diclofenac. And we’ve got three nurses there, and Meryl says, ‘Yes, I’ll give the rectal diclofenac’. The patient is in a position where they’re prone, they’re on their front, they’ve got one leg slightly above the other and it’s very easy to administer.

MR DUFFY: Well, again, that’s entirely new evidence, isn’t it, which is before the parties and the court for the first time on Day 1 of trial?”

164. Later in cross-examination, the Second Defendant agreed that he was present when Mr Deppeler said that if Diclofenac had been given, it would have been recorded in the electronic Medication Discharge Summary (core bundle/9/p. 996-998), and it was not recorded there. Mr Duffy said to the Second Defendant (transcript 16.03.26, p. 113), “And he said that, if diclofenac had been given, it would appear in this document [the electronic Medication Discharge Summary].” The Second Defendant ignored this and replied, “So on the report that I generated in connection with the nurses, the diclofenac was documented and given”. There was then the following exchange (transcript 16.03.26, p. 114):

“MR DUFFY: But, I mean, Nurse Meryl Bouwer should know, shouldn’t she, that it’s been given because she’s put it in your ERCP report?

SECOND DEFENDANT: Yes, yes, she should.

MR DUFFY: But she hasn’t included it here [in the Medication Discharge Summary], has she?

SECOND DEFENDANT: No.”

165. In re-examination, the Second Defendant’s recollection improved yet further and he could recall the words of conversation with the nurses (transcript 16.03.26, p. 151):

“A. I have very good recollection of sign-in, Nurse Meryl Bouwer having on the side, in front of the cabinets -- having the rectal indomethacin out, and of the instruction -- the conversation, ‘Meryl, can you give the suppository?’. The actual giving it, I wasn’t watching it, but she said, ‘Yes, got it out’ -- and the actual giving of it, the putting it in, I don’t normally watch because I don’t want to.”

166. It is said by the Second Defendant that after the conclusion of the ERCP and before the Second Defendant and nurses had left the theatre, there was a “read out loud” of all the prescription drugs that the Claimant had received, including Diclofenac. I repeat paragraphs 146 and 147 above.

167. Nurse Ferrari and Nurse Mondido both say they have no recollection of the procedure. They do not say that they remember the Second Defendant giving an oral instruction to administer Diclofenac.

Finding as to whether the Second Defendant gave the First Defendant’s nurses an oral instruction to administer Diclofenac

168. I find on the balance of probabilities that the Second Defendant did not give the First Defendant’s nurses an oral instruction to administer Diclofenac for the following reasons.

169. In his witness statement, the Second Defendant says (R/26/p. 217),

“38. It is my routine practice to ask for Diclofenac to be prescribed in all cases of ERCP that I perform at the start of the procedure.”

However, he does not say that he asked for Diclofenac to be administered.

170. The Second Defendant’s detailed evidence of orally requesting Diclofenac and it being administered was given for the very first time in cross examination on the first day of trial, 6½ years after the index event. He was still adding further detail in re-examination by Mr Perfect, for the first time reporting the conversation, ‘Meryl, can you give the suppository?’ and Nurse Bouwer’s reply, ‘Yes, got it out’.
171. I find that the Second Defendant offers no good reason for why this graphic account was not included in his witness statement, bearing in mind that it goes to a central issue in the case.
172. Diclofenac is not recorded in the consent form, which was completed by the Second Defendant during the consenting process 15 to 20 minutes before the ERCP, under the heading (core bundle/5/p. 779) “The procedure will involve rectal administration of drugs”. This box is not ticked, which is consistent with Diclofenac not being prescribed.
173. Although Mr Deppeler, Nurse Mondido and Nurse Ferrari say that it is commonplace for verbal directions to be given for the administration of Diclofenac, I find that there is no support in the evidence of the First Defendant that in this case the Second Defendant gave an oral instruction to administer Diclofenac.
174. Nurse Ferrari and Nurse Mondido both say in their witness statements that they have no recollection of the procedure on 16 July 2019. Mr Deppeler says in his witness statement (R/27/p. 228), “8. I have no recollection of this patient”.
175. Neither the Second Defendant, Mr Deppeler, Nurse Mondido or Nurse Ferrari say in their witness statements that Diclofenac was brought from the ward to the theatre. Further, I find that if Diclofenac had been brought from the ward, as a matter of law there should be a written prescription, and there was none.
176. In his witness statement at paragraph 7 (R/27/p. 228) and in his oral evidence, Mr Deppeler agreed that the Hospital protocol for drug administration was for the Consultant and the Nurses to record the medication given to a patient before or during a procedure in the Drug Prescription and Administration Chart. This was also the evidence of Nurse Ferrari in her witness statement (R/29/p. 240),

“The usual practice should also have been for Dr Reffit to enter on the drug administration chart that the Diclofenac had been given, and this would be countersigned by a member of nursing staff.”
177. Diclofenac is not recorded as having been prescribed or administered in the Drug Prescription and Administration Chart. Mr Deppeler says in his witness statement at paragraph 8 (R/27/p. 228),

“I can offer no explanation for the fact the Diclofenac was not recorded on the drug administration chart at the time of the Claimant’s procedure on 16 July 2019.”

178. I find that there is a very simple explanation: Diclofenac is not recorded on the Drug Prescription and Administration Chart because it was not prescribed, either in writing or orally.
179. The Second Defendant said in his oral evidence that there was (transcript 16.03.26, p. 150), “a sign-in, a World Health Organisation sign-in, where we talk about what's going to happen, we check that the consent form has been filled in, and then we say -- we preplan what's -- go through a checklist, but we preplan what's going to happen and then we follow the order of events”.
180. If this was true and the Second Defendant and the First Defendant’s nurses had checked the consent form in theatre, and had said out loud that Diclofenac had been administered, it becomes even more inexplicable how Diclofenac was not reordered in the Drug Prescription and Administration Chart and not signed by the First Defendant’s nurses and Second Defendant.
181. When the Second Defendant was asked in cross-examination why he had not stated in his witness statement that both at the sign in before the procedure and at the sign out after the ERCP had been completed, Diclofenac had been read out loud by him and the nurses, and the nurses inputted the premedication drugs, which were transferred by him into his ERCP report, the Second Defendant had no answer. He said (transcript 16.03.26, p. 113),
- “I wrote my witness statement because I thought best -- I'm not a lawyer. I did it as best as I thought fit. I didn't know that that -- I did the best job I could. I was trying to do what is my recollections for the day.”
182. I find this is no answer to why the Second Defendant did not state in his witness statement that:
- i) He had a detailed recollection of the ERCP
 - ii) There had been a read out loud of the drugs including Diclofenac, both before the procedure and after the procedure had been concluded
 - iii) The nurses inputted the premedication drugs and
 - iv) The premedication drugs inputted by the nurses were transferred into the Second Defendant’s ERCP report.
183. Further, as stated at paragraph 161 above, I find that the Second Defendant’s witness statement does not provide his “recollections for the day” but only states his usual practice.
184. Mr Deppeler said in cross-examination that if a nurse had administered Diclofenac, a record of it should have been made in the Medication Discharge Summary (transcript 16.03.26, p. 34-35),

“MR DUFFY: This is headed, ‘Medication discharge summary’;
is that right?

MR DEPPELER: Yes.

MR DUFFY: So if a nurse had administered diclofenac, the same
nurse should have gone on and made a record here electronically;
is that right?

MR DEPPELER: Yes.”

185. If Diclofenac had been read out loud by the Second Defendant and the First Defendant’s nurses after the ERCP when the WHO surgical safety checklist was completed and signed out at 17:55 by Nurse Bouwer (core bundle/7/p. 793), it is overwhelmingly likely that Nurse Bouwer would have included Diclofenac in the electronic Medication Discharge Summary six minutes later, at 18:01, if it had been administered.
186. Further, if there had been such a read out loud, it is inconceivable that Nurse Bouwer would have recorded 40mg Buscopan when that had not been prescribed and so would not have been read out loud.
187. I find that the Second Defendant’s evidence from the witness box, which grew on each telling, that he instructed the First Defendant’s nurses to administer Diclofenac and Diclofenac was administered by Nurse Bouwer is not true and I reject it. I find that this seriously undermines the Second Defendant’s credibility.
188. In this case there are two examples during the Claimant’s procedure of drugs being recorded as having been administered to the Claimant which had not been administered. As a consequence, the Court cannot consider the Defendant’s ERCP report as an accurate record of the drugs which were prescribed and administered. The Court must consider all of the evidence, including the Hospital records and the credibility findings the Court has made of the witnesses.
189. Firstly, in the WHO Surgical Safety Checklist, Endoscopy Only, dated 16 July 2019, signed in by Nurse Bouwer at 16:46 it states that the antibiotic prophylaxis Ciprofloxacin had been given (core bundle/7/p. 793).
190. On the pre-procedure checklist (on entry to the anaesthetic room) (core bundle/7/p. 791), signed by Nurse Ferrari, none of the options are selected against “Prescribed Pre medication given Yes No N/A”.
191. It was only as a result of RMO Clark-Morgan discovering at 19:00, one hour after the procedure had finished, that Ciprofloxacin had not been administered to the Claimant, that it was then administered after a written prescription had been provided in the electronic Medication Discharge Summary (core bundle/10/p. 2688). No regret for this was expressed by either Mr Deppeler, as the Manager of the Endoscopy Unit, or the Second Defendant.
192. The pre-procedure checklist and the WHO Surgical Safety Checklist are likely to have been signed within minutes of each other and show two nurses giving contradictory information as to whether the Claimant had received Ciprofloxacin. No explanation

was given by the First and Second Defendants in their witness statements or oral evidence for how this contradiction has occurred.

193. Secondly, Buscopan is recorded as having been given in a high dosage, 40 mg, on the electronic Medication Discharge Summary (Core bundle/9/p. 997). The Second Defendant said in his oral evidence that Buscopan had not been administered. I find it deeply troubling that neither the Second Defendant nor Mr Deppeler gave any evidence as to how this error had occurred. Neither of them expressed any regret that this had been wrongly recorded.
194. These two examples of Ciprofloxacin and Buscopan show that one cannot rely upon the medical records as being accurate. I find that in the present case, the evidence as a whole shows overwhelmingly that the Second Defendant's ERCP was wrong to record Diclofenac as having been administered.
195. I find that it was the Second Defendant's intention to prescribe Diclofenac, as recorded in his ERCP report, but that the evidence as a whole shows far beyond the balance of probabilities that Diclofenac was not prescribed by the Second Defendant, orally or in writing.

Finding as to whether First Defendant's nurses administered Diclofenac

196. In his closing submissions, Mr Cox says,

“11. ... However, any criticisms that the Court may have of the record keeping here are not incompatible with the core proposition of both Defendants' factual case which is essentially that the errors here are in documenting the prescription and administration of the medication properly rather than a failure by both the Defendants to provide medication that D2 contends he always prescribed.”
197. I reject this submission and find on the balance of probabilities that the Claimant was not administered Diclofenac.
198. My findings are entirely consistent with Diclofenac not having been administered. I have found:
 - i) The Claimant was not advised as part of the consenting process by the Second Defendant that Diclofenac would be administered rectally.
 - ii) There was no written prescription for Diclofenac.
 - iii) There was no oral instruction given by the Second Defendant to the First Defendant's nurses for Diclofenac.
199. I accept Professor Gilmore's evidence in his report at paragraph 2.5 (R/31/p. 258),

“No nurse would or should give a drug to a patient without it being prescribed on the patient's named prescription chart and without signing that it was administered at a particular date and time. Failing to do so is not a ‘minor clerical error’, as stated in

one witness statement from the nursing staff but ignoring a basic tenet of safe prescribing. I conclude that it was Dr Reffitt's intention to prescribe diclofenac and, if it was neither prescribed nor administered, this constitutes a breach of duty."

200. Unsurprisingly, in the light of Professor Gilmore's evidence, there is no evidence from Mr Deppeler, Nurse Mondido or Nurse Ferrari that Diclofenac was administered. Nurse Mondido and Nurse Ferrari both say they have no recollection of the ERCP.

201. In the First Defendant's Part 18 response, it is said (R/14/p. 93),

"d) Which of the three nurses recorded as being present had the responsibility for administering the Diclofenac?

Response: The First Defendant is not able to confirm which nurse administered the Diclofenac.

202. The Drug Prescription and Administration Chart records both the prescribing of drugs and the administration of drugs, including the dose and the route. It is signed by the surgeon and the nurses. Diclofenac is not recorded, which I find it would have been if it had been administered.

203. I have no hesitation in finding on the balance of probabilities that the Second Defendant did not instruct the First Defendant's nurses to administer Diclofenac and Diclofenac was not administered to the Claimant on 16 July 2019.

Law

204. The seminal statement of the standard of care required in clinical negligence cases was articulated by McNair J in *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582, 586 (authorities bundle/1/p. 7-8),

"The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art [...] in the case of a medical man, negligence means failure to act in accordance with the standards of reasonably competent medical men at the time. That is a perfectly accurate statement, as long as it is remembered that there may be one or more perfectly proper standards; and if he conforms with one of those proper standards, then he is not negligent [...] the real question is whether the defendants, in acting in the way they did, were acting in accordance with a practice of competent respected professional opinion ... he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art [...] Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view."

205. The test was reformulated by Lord Scarman in *Sidaway v Governors of Bethlem Royal Hospital* [1985] AC 871 at 881F (authorities bundle/2/p. 27):

“The *Bolam* principle may be formulated as a rule that a doctor is not negligent if he acts in accordance with a practice accepted at the time as proper by a responsible body of medical opinion even though the other doctors adopt a different practice.”

206. In *Maynard v West Midlands Regional Health Authority* [1984] 1 W.L.R. 634 (HL) Lord Scarman said at page 639,

“I have to say that a judge's 'preference' for one body of distinguished professional opinion to another also professionally distinguished is not sufficient to establish negligence in a practitioner whose actions have received the seal of approval of those whose opinions, truthfully expressed, honestly held, were not preferred. If this was the real reason for the judge's finding, he erred in law even though elsewhere in his judgment he stated the law correctly. For in the realm of diagnosis and treatment negligence is not established by preferring one respectable body of professional opinion to another. Failure to exercise the ordinary skill of a doctor (in the appropriate specialty, if he be a specialist) is necessary.”

Breach of duty of care – Second Defendant

207. I summarise below my factual findings, which are all made on the balance of probabilities:

- i) It was solely the Second Defendant's responsibility to decide what medication the Claimant required prior to, during or after the ERCP procedure on 16th July 2019.
- ii) It is agreed by the Defendants and I have found that the Claimant should have been advised that Diclofenac would be administered rectally.
- iii) I accept the evidence of the Claimant that he was not advised at the consultation with the Second Defendant on 14 June 2019 that Diclofenac would be administered rectally.
- iv) I find that the Claimant would have remembered if he was informed on 16 July 2019 that Diclofenac would be administered rectally and he would have remembered if Diclofenac had been administered. Both Dr Anderson and Dr Woodward agreed that given that the Claimant could remember the Xylocaine throat spray, he would have remembered being told that Diclofenac was going to be administered rectally.
- v) I find that the Defendants did not notify the Claimant on 16 July 2019 that Diclofenac was going to be administered rectally.

- vi) I find that by reason of Regulation 227 of the Human Medicines Regulations 2012/1916 a written instruction must be given in hospital for a prescription drug such as Diclofenac.
- vii) I find that if Diclofenac was administered, it should have been recorded on:
 - a) The Drug Prescription and Administration Chart (R/26/p. 226).
 - b) The electronic Medication Discharge Summary (Core bundle/9/p. 996-998).

Diclofenac is not recorded on either of these.

- viii) I find that, as the Second Defendant says at paragraph 34 of his witness statement (R/26/p. 217), it was “[his] usual practice to always prescribe Diclofenac either before or during an ERCP procedure in all cases in order to reduce the risk of post-procedure pancreatitis”. I find that the Second Defendant intended to give the First Defendant’s nurses instructions to administer 100mg Diclofenac rectally but failed to do so.
- ix) I find that Diclofenac was not administered to the Claimant on 16 July 2019.
- x) I find that the First Defendant’s nurses did not input premedication into the Second Defendant’s ERCP report (R/26/p. 221).
- xi) I find that the Second Defendant typed the ERCP report immediately after the surgery took place, as he said in his witness statement, dated 4 December 2024, (R/26/p. 216) at paragraph 27.

208. In the Consultant Gastroenterologists’ joint statement, they say (R/40/p. 522),

“2.11 k) If the Second Defendant intended to prescribe Diclofenac but failed to communicate this to nursing staff, would that be below a reasonable standard of care? All three experts agreed that this would not be an acceptable standard of care as the appropriate medication would not therefore be administered.”

209. I find on the balance of probabilities that the Second Defendant intended to prescribe Diclofenac but failed to communicate this to the First Defendant’s nurses and was thereby in breach of his tortious and contractual duty of care to the Claimant in failing to instruct the First Defendant’s nurses to administer Diclofenac.

Breach of duty of care - First Defendant

- 210. I find that having regard to my finding of fact that the Second Defendant did not provide a written prescription or an oral request to the First Defendant’s nurses to administer Diclofenac, it follows that the claim against the First Defendant must be dismissed.
- 211. The First Defendant’s position in its original defence, dated 22 January 2024, was that the Second Defendant did not prescribe Diclofenac to the Claimant and the First

Defendant's nurses did not administer it. In the Defence of the First Defendant it is said (R/9/p. 61),

“10.4 In this case, the First Defendant admits and avers that the medication prescribed to the Claimant by the Second Defendant and administered to the Claimant by the First Defendant in accordance with that prescription was that set out in the Endoscopy department drug prescription and administration chart referred to at paragraph 19(i) of the Particulars of Claim and in the other records referred to at paragraph 19 of the Particulars of Claim.

10.5 The First Defendant avers that at no stage prior to, during or after the ERCP on 16th July 2019 did the Second Defendant prescribe Diclofenac for the Claimant.

10.6 Hence, Diclofenac was not administered to the Claimant by any of the First Defendant's staff prior to, during or after the ERCP.”

212. Subsequently, the First Defendant filed an amended defence, dated 18 March 2025, in which it said (R/12/p. 81),

“The First Defendant avers that its nursing staff administered Diclofenac per rectum prior to the ERCP as directed by the Second Defendant but that the First & Second Defendants failed to record prescription or administration of the same in the drug charts.”

213. In the witness statement of Hazel Davies, Senior Associate Solicitor on behalf of the First Defendant, she says (R/30/p. 247),

“8. My client accepts that the Defence represents a fundamental change in direction by the First Defendant. The First Defendant wishes to adopt an entirely transparent approach to this change of position. Initially, a failure to record the Diclofenac medication (either by prescription or administration) in a drug chart was regarded as being determinative based upon the First Defendant's understanding of prescription practice and preliminary investigations. Those investigations comprised consideration of the records, and input from personnel at the London Bridge Hospital. However, subsequently, more extensive enquiries were undertaken with potential witnesses and an entirely different picture emerged in relation to the First Defendant's position. Lay witness evidence has been adduced on behalf of the First Defendant from the following individuals:

i) Phillip Deppeler – Endoscopy Manager at the London Bridge Hospital – statement dated 10 March 2025;

ii) Mara Ferrari – Nurse in theatre at the time of the Claimant's operation – statement dated 9 March 2025;

iii) Remeline Mondido – Scrub Nurse in theatre at the time of the Claimant's procedure – statement dated 11 March 2025.”

214. I find the reason given for the First Defendant's major change of position wholly unconvincing. It is said that a different picture emerged having regard to lay witness evidence. However, a different picture does not emerge from the three witness statements served by the First Defendant. Nurse Mondido and Nurse Ferrari say in terms that they have no recollection of the procedure (R/28/p. 234 and R/29/p. 240 respectively) and Mr Deppeler says he has no recollection of the Claimant (R/27/p. 228). Nurses Mondido and Ferrari do not say that the Second Defendant gave them a written prescription or oral instruction to administer Diclofenac and nor do they say that they administered Diclofenac.

215. I was not taken to any material which began to justify the First Defendant's change of position.

216. I find that the First Defendant's original defence was the correct position.

Causation

217. In the Particulars of Claim it is said (R/6/p. 36-37),

“32. The Claimant's injury, loss and damage was caused or materially contributed to by the negligence and/or breach of contract of the Defendants as set out above. Had the Diclofenac been prescribed and administered prior to the ERCP, the Claimant would have avoided pancreatitis; alternatively, the severity of his pancreatitis would have been reduced such that it would not have developed into necrotising pancreatitis. In any case the Claimant would have avoided all of the sequelae of the necrotising pancreatitis which includes the pleading at paragraph 29 above.”

218. The Claimant submits that on the balance of probabilities causation is proved on two bases:

- i) “But for” the breach of duty of care of the Second Defendant, the Claimant would have avoided pancreatitis.
- ii) The Claimant has suffered a material contribution in that the severity of his pancreatitis would have been reduced but for the negligence of the Second Defendant in failing to prescribe Diclofenac.

Statistics

219. The Defendants referred the Court to the following authorities on the application of statistical evidence.

220. In *Gregg v Scott* [2005] 2 AC 176 Lord Nicholls said (authorities bundle/4/p. 77-78),

“27. In cases of medical negligence assessment of a patient’s loss may be hampered, to greater or lesser extent, by one crucial fact being unknown and unknowable: how the particular patient would have responded to proper treatment at the right time. The patient’s previous or subsequent history may assist. No doubt other indications may be available. But at times, perhaps often, statistical evidence will be the main evidential aid.

28. Statistical evidence, however, is not strictly a guide to what would have happened in one particular case. Statistics record retrospectively what happened to other patients in more or less comparable situations. They reveal trends of outcome. They are general in nature. The different way other patients responded in a similar position says nothing about how the claimant would have responded. Statistics do not show whether the claimant patient would have conformed to the trend or been an exception from it. They are an imperfect means of assessing outcomes even of groups of patients undergoing treatment, let alone a means of providing an accurate assessment of the position of one individual patient.

...

32. The value of the statistics will of course depend upon their quality: the methodology used in their compilation, how up to date they are, the number of patients involved in the statistics, the closeness of their position to that of the claimant, the clarity of the trend revealed by the figures, and so on. But to reject all statistical evidence out of hand would not be acceptable. This argument, if accepted, would effectually nullify the use of statistics in all cases of delayed treatment save perhaps where the figures approached 0% or 100%. Despite its imperfection, in practice statistical evidence of a diminution in perceived prospects will often be the nearest one can get to evidence of diminution of actual prospects in a particular case. When there is nothing better courts should be able to use these figures and give them such weight as is appropriate in the circumstances. This conclusion is the more compelling when it is recalled that the reason why the actual outcome for the claimant patient if treated promptly is not known is that the defendant by his negligence prevented that outcome becoming known.”

221. Lord Hope said (authorities bundle/4/p. 96),

“Statistics may act as a guide. In some cases they may be the only guide that is available. But they are no more than a guide to that which must be proved. This is because the claim is personal to the individual. It is the effect of the injury on his own prospects of survival that sounds in damages, not the effect which injuries of that type may have on the population generally.”

222. In *Sienkiewicz v Greif (UK) Ltd* [2011] UKSC 10, Lady Hale said in respect of the use of statistics:

“170. However, I do agree with Lord Rodger that doubling the risk is not an appropriate test of causation in cases to which the Fairchild exception does not apply. Risk is a forward-looking concept – what are the chances that I will get a particular disease in the future? Causation usually looks backwards – what is the probable cause of the disease which I now have? Epidemiology studies the incidence and prevalence of particular diseases and the associations between both of these and particular variables in the diseased population. From these it is possible to predict that a particular percentage of the population, for example of women aged between 60 and 70, will contract a particular disease, for example, breast cancer. It is also possible to say that certain variables, such as life-style or age of first child-bearing, are associated with a greater chance of developing the disease. So a doctor will sensibly advise her patient to behave in a way which will reduce the risks. But if the disease materialises, the existence of a statistically significant association between factor X and disease Y does not prove that in the individual case it is more likely than not that factor X caused disease Y.

....

172. But as a fact finder, how can one ignore these statistical associations? Factfinding judges are told that they must judge a conflict of oral evidence against “the overall probabilities” coupled with the objective facts and contemporaneous documentation: see, for example, Robert Goff LJ in *Armagas Ltd v Mundogas SA (The “Ocean Frost”)* [1985] 1 Lloyd’s Rep 1, 57. Millions of pounds may depend upon their decision. Yet judges do not define what they mean by “the overall probabilities” other than their own particular hunches about human behaviour. Surely statistical associations are at least as valuable as hunches about human behaviour, especially when the judges are so unrepresentative of the population that their hunches may well be unreliable? Why should what a (always middle aged and usually middle class and male) judge thinks probable in any given situation be thought more helpful than well-researched statistical associations in deciding where the overall probabilities lie? As it seems to me, both have a place. Finding facts is a difficult and under-studied exercise. But I would guess that it is not conducted on wholly scientific lines. Most judges will put everything into the mix before deciding which account is more likely than not. As long as they correctly direct themselves that statistical probabilities do not prove a case, any more than their own views about the overall probabilities will do so, their findings will be safe.”

Odds ratio and relative risk ratio

223. In the joint statement of the Consultant Gastroenterologists, they say (R/40/p. 523),

“They agreed that the relative risk ratio rather than the odds ratio would be the correct statistical tool, equating to ‘balance of probabilities’ although the odds ratio and relative risk ratio would likely approximate closely.”

European Guideline for prophylaxis of post-ERCP pancreatitis

224. The European Society of Gastrointestinal Endoscopy has published guidance that strongly recommends the routine rectal administration of 100mg of Diclofenac or Indomethacin immediately before ERCP in all patients without contradictions to NSAID usage. In the European Society of Gastrointestinal Endoscopy (ESGE) Guideline: Prophylaxis of post-ERCP pancreatitis. J-M. Dumonceau et al. Endoscopy 2010; 42: 503–515 it is said (G, tab 57/p. 11-24 at p. 15),

“Drugs with proven efficacy

Nonsteroidal anti-inflammatory drugs (NSAIDs)

NSAIDs reduce the incidence of PEP [post-ERCP pancreatitis]; effective PEP prophylaxis has only been demonstrated using 100 mg of diclofenac or indomethacin administered rectally (Evidence level 1++). Routine rectal administration of 100 mg of diclofenac or indomethacin immediately before or after ERCP is recommended (Recommendation grade A).”

225. In J-M Dumonceau et al., Prophylaxis of post-ERCP pancreatitis: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Updated June 2014. Endoscopy 2014; 46: 799–815 it is said (G/58/p. 25-42 at p. 25),

“Main recommendations

1 ESGE recommends routine rectal administration of 100mg of diclofenac or indomethacin immediately before or after ERCP in all patients without contraindication.”

226. In J-M Dumonceau et al., ERCP-related adverse events: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. Endoscopy 2020; 52: 127-149, it is said (G/61/p. 73),

“MAIN RECOMMENDATIONS

Prophylaxis

1 ESGE recommends routine rectal administration of 100 mg of diclofenac or indomethacin immediately before endoscopic retrograde cholangiopancreatography (ERCP) in all patients without contraindications to nonsteroidal anti-inflammatory drug administration.

Strong recommendation, moderate quality evidence.”

227. In July 2023 the British Society of Gastroenterology (BSG) adopted the European Society of Gastrointestinal Endoscopy (ESGE) Guideline of 2020.

American Guideline for post-ERCP pancreatitis prevention strategies

228. The American Society for Gastrointestinal Endoscopy has also provided guidelines on the prevention of post-ERCP pancreatitis. In the American Society for Gastrointestinal Endoscopy guideline on post ERCP pancreatitis prevention strategies: summary and recommendations. Buxbaum JL et al. Gastrointestinal Endoscopy 2023; 97(2): 153-162) it is said (G/62/p. 131-132),

“Question 1: In unselected patients undergoing ERCP, should rectal NSAIDs be given to prevent PEP?

Recommendation 1: Among unselected patients undergoing ERCP, the ASGE recommends periprocedural rectal NSAIDs should be given to prevent PEP (Strong recommendation/Moderate quality of evidence).

...

In summary, given the significant reduction in PEP, cost-effectiveness, and minimal AEs, the panel made a strong recommendation for use of rectal NSAIDs in unselected patients undergoing ERCP. The overall quality of the evidence was moderate.”

Issues on “but for” causation

229. On “but for” causation there are the following issues:
- i) Is it appropriate to rely upon sub-group analysis?
 - ii) If so, is it appropriate to rely on the studies selected by Professor Gilmore?
 - iii) Should the Court decide the case on the balance of probabilities, i.e. more than 50%, or on the scientific standard, namely a confidence interval of 95%?

Is it appropriate to rely upon sub-group analysis?

Claimant’s submissions

230. The Claimant submits that both the European 2020 Guideline (the European Guideline) and the American 2023 Guideline (the American Guideline) give a strong recommendation, backed by moderate evidence, that NSAID should be administered to all patients without contraindication. The European Guideline states, “NSAIDs reduce the incidence of PEP”. The American Guideline says, “given the significant reduction in PEP ... the panel made a strong recommendation for use of rectal NSAIDs in unselected patients undergoing ERCP”.

231. The Claimant acknowledges that the American Society for Gastrointestinal Endoscopy performed their own meta-analysis in 2023 and came to an odds ratio of 0.49 (G/62/p. 131) and concluded that “This means that using rectal NSAIDs is associated with a 50% reduction in the risk of PEP”. However, the Claimant submits that this meta-analysis includes NSAIDs which are known to be ineffective in avoiding pancreatitis and routes of administration (orally, intravenously and intramuscularly) which are known to be ineffective in avoiding pancreatitis.
232. Professor Gilmore considered subgroups from two meta-analyses, namely:
- i) The meta-analyses laid out in the supplement to the European Guideline
 - ii) Lyu et al’s study: What is the impact of nonsteroidal anti-inflammatory drugs in the prevention of post-endoscopic retrograde cholangiopancreatography pancreatitis: a meta-analysis of randomized controlled trials the ESGE (2020) guidelines. BMC Gastroenterology (2018) 18:106 (G/64/p.147-162).

The European Guideline

233. Professor Gilmore says in his report, dated September 2025 (R/31/p. 259-260),

“2.8 ... The best review of the evidence is in the ERCP Adverse Events Guideline of the European Society of Gastrointestinal Endoscopy (2020), and the relevant table 3s is included as an appendix to this report. Overall, the table confirms a benefit from administration of an NSAID, but it is not clear that it makes the prevention of pancreatitis more likely than not. However, the evidence review includes different NSAIDs and routes of administration, and in the specific case of rectally administered diclofenac there is a better than 50% chance of preventing pancreatitis in 9 of 11 available studies, reducing the risk usually to about 40%. From this I conclude that, if the court finds that diclofenac was not given, it is more likely than not that pancreatitis would have been prevented by its rectal administration.”

234. Professor Gilmore says in the joint statement that (R/40/p. 524-525),

“While accepting that the meta-analyses laid out in the supplement to the ESGE (2020) guidelines utilise overlapping studies, it is notable that in the 7 meta-analyses that looked at the risk ratio of rectal diclofenac, all found a value of less than 0.50 (0.24-0.41) and superiority over indomethacin.

ITG concludes that, if the court finds that rectal diclofenac was not given and should have been, on the balance of probabilities pancreatitis would have been avoided.”

Lyu et al

235. Professor Gilmore says in the Consultant Gastroenterologists' joint statement that Lyu et al is the only study to look specifically at individual drugs and routes of administration. He says (R/40/p. 524),

"IG agrees with JW that a recent and helpful meta-analysis is provided by Lyu et al, and notes also that of Liu et al (both are published in 2018 and include 21 and 19 randomised controlled trials (RCTs) respectively). Lyu et al is the only one to look specifically both at individual drugs and routes of administration, and so there are data specifically on rectal diclofenac, the drug and route under consideration in this case. 330 patients received diclofenac and 338 patients placebo. The risk ratio with rectal diclofenac was 0.38, giving a risk reduction of 62%."

236. In the Consultant Gastroenterologists' joint statement, Professor Gilmore says (R/40/p. 524-525),

"IG understood JW's wish to bring scientific validity to the question by relying on the confidence intervals of 95% ie the conclusion is likely to be correct 19 times out of 20. In order to achieve that, JW has amalgamated data from other drugs, usually indomethacin, and other routes of administration, such as oral or by injection. However, in IG's opinion this fails to answer the question posed by the court, namely if it finds that diclofenac 100 mg per rectum was not administered and should have been, if it had been administered pre-operatively would the claimant have avoided pancreatitis on the balance of probabilities. In his view, this means that evidence regarding rectal diclofenac only, as opposed to other drugs and/or other routes, should be considered. The test should be that the relative risk (preferably) or odds ratio should be reduced below 0.5. It will be for the court to decide whether or not to deviate from the principle of balance of probabilities and instead take into account the possibility that the balance of probabilities does not reach the 95% confidence limit. IG does not accept that the different routes of administration and different drugs used can be amalgamated. Indeed the current evidence suggests that diclofenac is more effective than indomethacin and that the rectal route is more effective than others."

Defendants' submissions

237. The Defendants submit that the experts agree that the meta-analyses show a relative risk which is close to but not below 50%.
238. In his closing submissions, Mr Cox argues,

“5 (f) D1 submits that the whole purpose of meta-analyses is to combine what would otherwise be small and unreliable trials to get some degree of reliability. Dr. Woodward explained how this irons out the differences and “noise” from multiple studies to allow confidence in the conclusions. Prof. Gilmore accepted that engaging in sub-group analysis necessarily means weakening the data to some extent, although he maintained it was appropriate in this case. However, D1 submits that this makes providing support for any particular view based on sub-group analysis dangerous.

(g) This can be demonstrated by a very simple review of the numbers involved in this case. In the whole of the *Lyu et al* paper [G147] there are 6,134 patients whereas in the 5 studies within *Lyu et al* that Prof. Gilmore relies on (see Fig 6 [G154] and replicated below) there are just 638 cases (about 11% of the study total).”

239. Dr Woodward says in the Consultant Gastroenterologists’ joint statement (R/40/p. 524),

“In JW’s opinion such subgroup analysis cannot be used as evidence that the Claimant would have avoided pancreatitis had he been given rectal NSAID (on the assumption that he was not) as:

a) This is a small subgroup - it is not intended that subgroup analysis is used in this way as:

b) There is high statistical uncertainty (of 40%, which crosses the 50% boundary)

...

It is logical in JW’s opinion to use the results of the meta-analysis itself (rather than small, highly variable subgroup analysis) to inform opinion in this setting, which is, that with statistical confidence, NSAIDs can prevent post procedural pancreatitis but the magnitude of this benefit is less than 50%. Therefore on balance of probability, pre-procedural diclofenac would not have prevented post-ERCP pancreatitis in this case had it not been given already.”

240. In the joint statement, Dr Anderson says (R/40/p. 523),

“**MA’s opinion was that** it would be statistically inappropriate to break down the meta-analyses that had led to the relevant guidance but also accepted that he is not an expert in statistics. He is of the opinion, as outlined by JW below, that the balance of probability that rectal diclofenac (or indomethacin) would have prevented the episode of pancreatitis is less than 50%.”

241. In cross-examination, Dr Anderson agreed that:

- i) The administration of NSAIDs intramuscularly, orally and intravenously had been shown not to work;
- ii) When it came to an analysis for this court's purpose, not statistical purposes, the Court should exclude consideration of NSAIDs which were administered intramuscularly, orally and intravenously.

242. Dr Anderson said (transcript 17.03.26, p. 95-96),

“MR DUFFY: Yes. I asked whether you agreed that intramuscular, oral and IV have been shown not to work. That was the question.

DR ANDERSON. Yes, from all of these meta-analyses --

JUDGE ROBERTS: Do you agree?

DR ANDERSON. I do, yes.

MR DUFFY: So when it comes to an analysis for the court's purpose, not for statistical purposes, the court should exclude consideration of the drugs which I've referred to and the methods of administration which I've referred to? Do you agree with that?

DR ANDERSON: Yes.”

Findings as to whether it is appropriate to use sub-group analysis

243. Bearing in mind that the Second Defendant's intention was to administer 100mg Diclofenac rectally preoperatively, I accept Professor Gilmore's evidence that the question for this Court is: if Diclofenac had been administered rectally pre-operatively as intended, on the balance of probabilities would the Claimant have avoided pancreatitis.

244. Mr Perfect says in his closing submissions,

“21. The question that Professor Gilmore poses as the one the court needs to answer is whether rectal diclofenac more likely than not prevents PEP. That is not the court's question. The court is not tasked with making a general finding, whether based on statistics or otherwise. Rather, the court is tasked with making a finding that is specific to the Claimant, and only the Claimant.”

245. I find that contrary to Mr Perfect's submission, Professor Gilmore's evidence is that one should not ask a general question but a question specific to the Claimant, namely if 100mg Diclofenac had been administered rectally pre-procedure, as intended by the Second Defendant, on the balance of probabilities would the Claimant have avoided pancreatitis. It is for that reason that Professor Gilmore says that one should exclude studies involving NSAIDs that have been administered orally, intramuscularly or intravenously rather than rectally, because it is common ground that those routes of

administration are ineffective. By parity of reasoning, Professor Gilmore says that the Court should base its analysis on the administration of Diclofenac because that was the NSAID intended to be administered by the Second Defendant and Diclofenac has been shown to be more efficacious than Indomethacin in preventing pancreatitis.

246. I find that applying the guidance of Lord Nicholls at paragraph 32 of *Gregg v Scott* (supra),

“The value of the statistics will of course depend upon ... the closeness of their position to that of the claimant.”

the statistics closest to the position of the Claimant are those involving the administration of Diclofenac rectally preoperatively. I accept Professor Gilmore’s evidence that it is appropriate to carry out a sub-group analysis in order to answer the question before the Court, ensuring that the statistics being used are close to the position of the claimant.

247. I accept Professor Gilmore’s evidence that the number of patients (668) in the five studies in Lyu et al which provide data specifically on rectal Diclofenac and the number of patients in the seven studies which provided data specifically on rectal Diclofenac in Table 3s to the European Guideline are numbers which are often used in meta-analysis and there is nothing unusual about them. Professor Gilmore said of the numbers in the five studies in Lyu (transcript, 17.03.26, p. 21, line 25 – p. 22, line 3),

“That’s the sort of numbers that are often used in meta-analysis. There’s nothing unusual - there’s nothing illegal or unusual about using meta-analysis on 600 patients.”

Distinguishing between different routes of administration of Diclofenac

248. In his opening skeleton argument, Mr Perfect accepts Professor Gilmore’s evidence that there are differing rates of risk of PEP according to the type of NSAID which is administered and the mode of administration and that this is relevant when considering the statistical risk of avoiding PEP. Mr Perfect says,

“16. ... Yet studies show apparently differing rates of risk of PEP according to type of NSAID and mode of administration. That is of relevance when considering statistical risk of avoiding PEP.”

249. All three Consultant Gastroenterologists accepted that the administration of NSAIDs intramuscularly, orally or intravenously had been shown to be ineffective to avoid pancreatitis and statistics from studies based on these methods of administration should be excluded when considering “but for” causation.

250. Dr Woodward says in his report, dated October 2025 (R/35/404),

“Numerous studies and meta-analyses have been published regarding the use of NSAIDs in both high and standard risk procedures. The findings suggest that the administration of NSAIDs is only effective if given by rectum rather than intravenously or by mouth.”

251. Dr Woodward agreed in cross-examination that the Court should exclude consideration of drugs and methods of administration which have been found to be ineffective (transcript, 17.03.26, p. 95-96),

“MR DUFFY: Yes. I asked whether you agreed that intramuscular, oral and IV have been shown not to work. That was the question.

A. Yes, from all of these meta-analyses --

JUDGE ROBERTS: Do you agree?

A. I do, yes.

MR DUFFY: So when it comes to an analysis for the court's purpose, not for statistical purposes, the court should exclude consideration of the drugs which I've referred to and the methods of administration which I've referred to? Do you agree with that?

A. Yes.”

252. Dr Anderson also agreed in cross examination that the Court should exclude consideration of drugs which have been found to be ineffective and drugs administered intramuscularly, orally or intravenously (transcript 17.03.26, p. 95-96),

“MR DUFFY: Yes. I asked whether you agreed that intramuscular, oral and IV have been shown not to work. That was the question.

DR ANDERSON. Yes, from all of these meta-analyses --

JUDGE ROBERTS: Do you agree?

DR ANDERSON. I do, yes.

MR DUFFY: So when it comes to an analysis for the court's purpose, not for statistical purposes, the court should exclude consideration of the drugs which I've referred to and the methods of administration which I've referred to? Do you agree with that?

DR ANDERSON: Yes.”

253. The Second Defendant also agreed that NSAIDs were ineffective if administered intravenously, saying in re-examination (transcript 16.03.26, p. 148),

“For a long time it was being performed intravenously, which is not what the trials have shown to be effective.”

Finding

254. I find that all three Consultant Gastroenterologists agree that the only effective method of administering NSAIDs is rectally. I find that the Court should consider studies where NSAIDs were administered rectally because these studies are closest to the position of the Claimant, and the question before the Court is whether on the balance of probabilities if 100mg Diclofenac had been administered rectally to the Claimant, this would have prevented pancreatitis.

Distinguishing between Diclofenac and Indomethacin

255. I repeat paragraph 248 herein.
256. Professor Gilmore, Dr Woodward and Dr Anderson agree that there has not been a head-to-head study between Diclofenac and Indomethacin to determine efficacy, rather the effect of each drug has been examined against a control.
257. While I bear in mind that the Consultant Gastroenterologists are not pharmacologists, I accept the evidence of Professor Gilmore that although Diclofenac and Indomethacin are the same class of drug, they do not act in the same way. Professor Gilmore said in re-examination (transcript 17.03.26, p. 69),
- “...they have differences, differences in other pathways they could affect. There’s these ion channels that allow potassium and sodium in and out of cells that are thought to be important in inflammation and there is evidence that diclofenac is effective against those.”
258. This is also confirmed by Lyu et al in their paper, where they say (G/64/p. 158),
- “The difference between indomethacin and diclofenac may be related to their differences in inhibition of phospholipase A₂”
259. Professor Gilmore says in the joint statement (R/40/p. 524-525),
- “The current evidence suggests that diclofenac is more effective than indomethacin and that the rectal route is more effective than others”.
260. Professor Gilmore referred to table 3s in the appendix to the European Guideline (G/61/p. 107-113). In table 3s there are seven meta-analyses which deal specifically with rectal NSAIDs and are split by drug, namely Diclofenac or Indomethacin. Table 3s shows that in all seven, the risk ratio or odds ratio was below 0.5 for rectal Diclofenac:
- i) Yu 2018 (R/31/p. 263): OR 0.27
 - ii) Yang 2017 (R/31/p. 264): RR 0.29
 - iii) Shen 2017: RR 0.29
 - iv) Hou 2017: RR 0.41

- v) Vadala di Prampero 2016 (R/31/p. 265): OR 0.24
 - vi) Sethi 2014 (R/31/p. 265): RR 0.35
 - vii) Sun 2014: RR 0.28.
261. Table 3s shows that the risk ratio or odds ratio was above 0.5 for rectal Indomethacin:
- i) Yaghoobi 2018: OR 0.56
 - ii) He 2018: RR 0.63
 - iii) Yu 2018: OR: 0.54
 - iv) Garag 2018: RR 0.6
 - v) Yang 2017: RR 0.6
 - vi) Feng 2017: RR 0.67
 - vii) Inamdar, 2017: RR 0.59
 - viii) Wan, 2017: RR 0.58
 - ix) Shen, 2017: RR 0.67
 - x) Hou, 2017: RR 0.58
 - xi) Vadala di Prampero, 2016: OR 0.59
 - xii) Shi, 2015: RR 0.51
 - xiii) Sethi, 2014: RR 0.51
 - xiv) Sun, 2014: RR 0.53
262. Professor Gilmore and Dr Woodward agree that a recent and helpful meta-analysis is provided by Lyu et al, which was published in 2018 and analyses 21 randomised controlled trials (RCTs) (G/64/p. 147-162). This study looks specifically at individual drugs and routes of administration. Therefore, there is data specifically on rectal Diclofenac. 330 patients received Diclofenac and 338 patients a placebo. The risk ratio with rectal Diclofenac was 0.38, giving a risk reduction of 62%, which satisfies the balance of probabilities standard of proof.
263. In Lyu et al, Figure 5 (G/64/p. 153) provides the following risk ratios for pancreatitis in five studies in which Diclofenac was administered rectally:
- i) Murray: 0.4
 - ii) Khoshbaten: 0.15
 - iii) Otsuka: 0.21

- iv) Lua: 1.9
 - v) UCAR (1): 0.14
264. In four of these five studies, the risk ratio if Diclofenac is administered rectally is below 0.5. The average remains below 0.5 even if the risk ratio of 1.9 is included from the Lua study, which was clearly an outlier.
265. Mr Cox submits in his closing submissions at paragraph 5 h),
- “The authors of Lyu et al state in their paper [G154] that; ‘Our meta-analysis showed that the rectal administration of NSAIDs might be the most effective in decreasing the incidence of PEP. Further subgroup analysis showed that indomethacin and diclofenac were able to reduce the incidence of PEP significantly compared with the placebo control. However, no differences were observed between the two drug groups’.”

Finding

266. I accept Professor Gilmore’s analysis that if one considers the seven studies at table 3s of the European Guideline and the five studies in Lyu et al in which Diclofenac was administered rectally, it can be seen that Diclofenac administered rectally is more efficacious in preventing pancreatitis and reduces the relative risk ratio below 50%.
267. I find that if one uses the meta-analyses, one is using drugs and means of administration which are known to be either less effective than the administration of Diclofenac rectally or not effective at all. The meta-studies have used NSAIDs administered intramuscularly, orally and intravenously, which are known not to reduce pancreatitis and Indomethacin, which can be seen to be less efficacious than Diclofenac.
268. I find that studies involving Diclofenac administered rectally should be considered because they are closest to the position of the Claimant and the Court is tasked with considering whether 100mg Diclofenac administered rectally to the Claimant would on the balance of probabilities have prevented pancreatitis.

Is it appropriate to rely on the studies selected by Professor Gilmore?

Defendants’ submissions

269. Mr Cox makes three submissions, which are supported by Mr Perfect.
270. Firstly, Mr Cox submits that three of the five studies in Lyu et al which involved only Diclofenac administered rectally, namely Khoshbaten, Lua and Murray, concern specifically selected high-risk cases, whereas the Claimant was low to medium risk or low risk. He says these three studies do not match the Claimant’s risk. They constitute 464 of the total 668 patients, or 69% of the patients in the five studies relied upon by the Claimant
271. Dr Woodward said in cross-examination that to compare the Claimant with patients who were high risk was like comparing the Claimant’s case with a different procedure (transcript 17.03.26, p. 115).

272. However, Dr Woodward also said that based on the literature it was not possible to say whether the efficacy of Diclofenac was different in different risk groups. He said (transcript, 17.03.26, p. 117-118):

“The evidence actually is still somewhat contentious on whether it’s better in high-risk groups than low-risk groups. ... To be honest, we still don’t really fully understand how it’s working and therefore I think we would need to know that before we could say that with any clarity, and of course what we’re looking at is the data, and the data is still somewhat contentious on whether high risk -- the benefit is in high risk more than in the low risk group.”

273. Secondly, Mr Cox said that in Lyu et al the authors said that no differences were observed between Diclofenac and Indomethacin (G/64/p. 154),

“Our meta-analysis showed that the rectal administration of NSAIDs might be the most effective in decreasing the incidence of PEP. Further subgroup analysis showed that indomethacin and diclofenac were able to reduce the incidence of PEP significantly compared with the placebo control. However, no differences were observed between the two drug groups.”

274. Thirdly, Mr Cox says that there is a difficulty with the Otsuka study in Lyu et al as to how pancreatitis was defined.

275. In addition to the submissions made by Mr Cox, Mr Perfect makes the following submissions.

276. Firstly, in his closing submissions he says at paragraph 24,

“(2) Dosage – Otsuka involved patients who received no more than 50mg diclofenac, in some cases even less. The Claimant’s intended dose was more than double that, at 100mg. That study constituted 104 of the total 668, or 15.6%.

277. Secondly, in his closing submissions he says at paragraph 24,

(3) Timing – Ucar (1) involved the giving of diclofenac at least 30, and perhaps as much as 90 minutes prior to procedure. Murray involved giving 2 hours before procedure. Khoshbaten involved giving up to 1 hour after procedure. The Claimant received his diclofenac but a few minutes before procedure.”

278. Thirdly, Mr Perfect says in his closing submissions at paragraph 26,

“(4) Nor does Professor Gilmore’s subgroup analysis reflect the materially lower incident of PEP in the hands of Dr Reffitt, which is also a relevant characteristic.”

Claimant's submissions

279. Regarding Mr Cox's first point, Professor Gilmore said in cross-examination:

i) (transcript 17.03.26, p. 24),

"I know from the evidence that there is no or unlikely to be any difference in the efficacy between high risk and average risk."

ii) (transcript 17.03.26, p. 26),

"There is no strong evidence that there's any difference in response between high and low risk"

280. Professor Gilmore said in re-examination (transcript 17.03.26, p. 67),

"MR DUFFY: My question is this: is there any reason that diclofenac would be more effective in a high-risk case than an average-risk case?"

PROFESSOR GILMORE: Clearly the high-risk case is by definition more at risk of getting pancreatitis, but I don't know any particular reason why diclofenac would be less or more effective.

MR DUFFY: Thinking about it this way, if you're at low risk of getting pancreatitis, I mean, would that make it easier or harder for diclofenac to work, if I can put it like that?

PROFESSOR GILMORE: I don't think I've got the evidence to answer that, but I would expect, if anything, diclofenac would be less of a hard job to do if there wasn't high risk. For example, you know, if the patient's pancreatic duct is cannulated or something like that, that would put them at higher risk and the diclofenac would have a bigger job to do.

MR DUFFY: Just follow that through mechanically. So why is – why would it be harder?

PROFESSOR GILMORE: Because there would be an inflammatory -- more likely be an inflammatory reaction triggered that needed dampening down."

281. Regarding Mr Cox's second point that in Lyu it was said that no differences were observed between Diclofenac and Indomethacin, Professor Gilmore said that this statement had to be looked at in context. The meta-analysis carried out by the writers of the Lyu et al paper did not compare Diclofenac administered rectally and Indomethacin administered rectally. They say (G/64/p. 156),

"No study has compared rectal indomethacin and diclofenac in a head-to-head trial to see if there is any difference in the efficacy between these 2 agents."

282. The Defendants rely upon figure 5 in the Lyu report (G/64/p. 153), which provides a combined risk ratio of 0.54. However, this table differentiates by route rather than by drug and includes Diclofenac and Indomethacin (and also Naproxen in the case of the Mansour-Ghanaei study) without differentiating between them. As Professor Gilmore said in cross-examination, the greater number of Indomethacin patients had “swamped the Diclofenac data” in figure 5 (transcript 17.03.26, p. 21). Professor Gilmore relied upon the seven studies in the European Guideline and the five studies in Lyu et al which show that the results for Diclofenac were better than those for Indomethacin in terms of risk ratios and odds ratios.

Findings

283. Firstly, I find that the evidence given in the present case shows on the balance of probabilities that there is no difference between the efficacy of Diclofenac in high-risk cases and low to medium-risk or low-risk cases for the following reasons:
- i) The European Guideline and the American Guideline recommend that an NSAID should be administered to all patients without contraindication. The European and American Guidelines make no distinction between high-risk and low-risk patients, which suggests that Diclofenac will be efficacious in preventing pancreatitis in cases of all risk level. Indeed, the European Guideline from 2010 stated (G/57/p. 15), “NSAIDs reduce the incidence of PEP”.
 - ii) In the present case, the Second Defendant’s evidence in his witness statement is that (R/26/p. 217),

“34. ... it is my usual practice to always prescribe Diclofenac either before or during a ERCP procedure in all cases in order to reduce the risk of post-procedure pancreatitis.”
 - iii) The Second Defendant did not say that he drew any distinction between patients with high and low levels of risk of pancreatitis.
 - iv) I accept the evidence of Professor Gilmore and Dr Anderson that there is no evidence that Diclofenac is more efficacious in high-risk cases than in low-risk cases. I further accept Professor Gilmore’s evidence that the fact that a person is at a higher risk of getting pancreatitis only means that they are more likely to develop pancreatitis, not that there is any reason why Diclofenac would be less or more effective. As Professor Gilmore said,
 - a) (transcript 17.03.26, p. 24),

“I know from the evidence that there is no or unlikely to be any difference in the efficacy between high risk and average risk.”
 - b) (transcript 17.03.26, p. 26),

“There is no strong evidence that there’s any difference in response between high and low risk”

284. Dr Anderson agreed in cross-examination that there was no reason to think that Diclofenac would work better with high-risk patients than with low-risk patients (transcript 18.03.26, p. 25),

“MR DUFFY: There’s no reason, is there, why diclofenac should work better in a high-risk case than a low-risk case?

DR ANDERSON: No, I don't think so. No.”

285. I find that there is no basis for Dr Woodward’s comment that comparing the Claimant’s case with high-risk patients is like comparing the Claimant’s case with a different procedure. Dr Woodward did not refer to any evidence showing that Diclofenac would work better in a high-risk case than a low-risk case and said that nobody really knew how Diclofenac worked in preventing pancreatitis.

286. Secondly, I find that the statement in Lyu et al that no differences were observed between Diclofenac and Indomethacin has to be looked at in context. As the writers of the Lyu et al paper say, “No study has compared rectal indomethacin and diclofenac in a head-to-head trial to see if there is any difference in the efficacy between these 2 agents”. I find that Professor Gilmore has demonstrated cogently and convincingly that if one analyses the seven studies in the European Guideline and the five studies in Lyu et al, it can be seen that Diclofenac administered rectally is more efficacious than Indomethacin and reduces the risk of pancreatitis below 50%.

287. Thirdly, I find that the Otsuka study did apply the usual Cotton criteria to define pancreatitis. In cross-examination Mr Cox put to Professor Gilmore that one would expect the Cotton criteria to be used to define pancreatitis (transcript 17.03.26, p. 30). Professor Gilmore pointed out that in the Otsuka study it is said (G/67/p. 184),

“The primary outcome measure was the occurrence of PEP, defined by the criteria of Cotton et al. as the development of abdominal pain and elevation of the serum amalyse level to greater than three times the upper normal limit within 24 h after ERCP.”

288. Regarding Mr Perfect’s additional point that the Otsuka study in Lyu et al involved patients who received no more than 50mg, whereas the Claimant’s intended dosage was 100mg, I find:

- i) Neither Dr Woodward nor Dr Anderson submitted that the dosage of the NSAID was material. There is no evidential foundation for Mr Perfect’s submissions.
- ii) In any event, the Second Defendant’s intended dosage of Diclofenac was 100mg, which is the optimal dosage. This was the dosage recommended in the European Guideline (G/58/p. 25) and the American Guideline (G/62/p. 131). Therefore, the probability of the Claimant developing pancreatitis would have been less likely than in the patients in the Otsuka study who received no more than 50mg. The risk ratio for the patients in the Otsuka study developing pancreatitis was 0.21, which is far in excess of 50%. As the Second Defendant intended the optimal dosage of 100mg to be administered to the Claimant, the Claimant’s risk of developing pancreatitis would have been even lower.

289. Regarding Mr Perfect's submission as to the timing of the administration of Diclofenac being different in three of the five studies in Lyu et al in which Diclofenac was administered rectally, I find:
- i) Neither Dr Woodward nor Dr Anderson submitted that the timing of the administration were material. Mr Perfect's submission has no evidential foundation.
 - ii) The European Guideline recommends that the NSAID is administered before the ERCP, as was the intention of the Second Defendant in the present case. Therefore, I find that if Diclofenac had been administered rectally before the ERCP as the Second Defendant intended, it is likely that it would have been at least as efficacious as in the studies in Lyu et al.
290. I reject Mr Perfect's submission that Professor Gilmore's sub-group analysis does not reflect the materially lower incidence of PEP in the hands of the Second Defendant. The Second Defendant's lower incidence of PEP has to be looked at in the context that he says in his witness statement (R/26/p. 217),
- “34. ... it is my usual practice to always prescribe Diclofenac either before or during a ERCP procedure in all cases in order to reduce the risk of post-procedure pancreatitis.”
291. In the present case, I have found that the Second Defendant did not prescribe Diclofenac and it was not administered and therefore the basis for the Second Defendant's lower incidence of PEP falls away.
292. I conclude that it is appropriate to rely on sub-group analysis and on the seven studies in table 3s of the European Guideline, where Diclofenac was administered rectally, and the five studies in Lyu et al. I further find on the balance of probabilities that 100mg Diclofenac administered rectally pre-procedure is more efficacious in preventing pancreatitis than Indomethacin.

Standard of proof and confidence interval

Defendants' submissions

293. Neither Dr Woodward nor Dr Anderson argued in their reports, dated October 2025 (R/35/p. 365-422) and 31 October 2025 (R/36/p. 423-433) respectively, that the Claimant had to satisfy a confidence interval of 95%.
294. When the Consultants in Gastroenterology met for their joint meeting, they had an agenda. That agenda did not ask a question about confidence intervals. However, it can be seen from the joint statement (R/40/p. 517-528) that Dr Woodward introduced confidence intervals for the first time.
295. In his closing written submissions, Mr Duffy says at paragraph 12 b,
- “In C's submission [Dr Woodward] had set out in a pursuit of statistical certainty which is not the test which is to be applied. Despite relying on the risk ratio (the weighted average outwith brackets) in joint statement, the test he said that C had to meet

ballooned even further at trial: now the entire 95% confidence interval bracket had to fall below 0.5 for C to succeed”

296. Dr Woodward said in cross-examination (transcript, 17.03.26, p. 101-103):

“MR DUFFY: I think effectively what you’re saying to his Lordship is that, in all these papers we’ve been through at length, the entire range in the brackets needs to be below 0.5. Is that the test which you say --

DR WOODWARD: Yes, that is how this would be interpreted by anybody who is used to looking at meta-analyses and uses meta-analyses in clinical practice or to inform practice.

MR DUFFY: But this range is done on a 95% confidence interval --

DR WOODWARD: Yes.

MR DUFFY: -- so 19 out of 20 times the answer is within this range, isn't it?

DR WOODWARD: So confidence intervals, yes, it’s set at 95% confidence. That’s a -- that is what we use in medical science and in science, and for good reasons, and the range of 50% or a lower range than 95% can’t be applied here. This is a scientific answer. We need to provide the court with the best answer we can, not any answer, and so we can’t apply balance of probabilities to provide the probability to go into a balance of probabilities. That’s more like a meta-balance of probabilities. It has to -- we have to have a scientific standard, which is this. It’s not -- science can’t be based on balance of probabilities, ‘Is it more or less than 50%?’, and you can’t then use that number to say, ‘Well, given that number that we’ve got, we’ll put that into a balance of probabilities and make an argument from it’. It has to be -- this is a scientific number to give us the best answer and the best idea of what that outcome is.

MR DUFFY: Let's put it another way. Well, I'll ask this first, actually. You heard Professor Gilmore's evidence that he has looked at a 70% confidence interval in relation to the diclofenac rectal-only administration figure in Lyu, and if you use that level of confidence instead of 95, the range goes below 0.5. Do you agree with that?

DR WOODWARD: I haven't done the statistics myself but it's quite possible that if you -- well, it's possible that -- probable that, if you reduce the certainty, you'll be able to find whatever number you want because then the range of uncertainty is so great that it becomes a meaningless statistic.

...

MR DUFFY: Professor Gilmore says, "I've run 70% confidence interval on the range in Lyu for the five studies and, if I do that, it all comes in under 0.5".

...

MR DUFFY: I think the position, amalgamating your two answers, is that you haven't run that yourself, that assessment of a 70% confidence, and it's possible that that does as Professor Gilmore says.

DR WOODWARD: That sounds perfectly plausible, that if you're prepared to sacrifice any confidence in the answer you get, that you will be able to get an answer that you want."

Claimant's submissions

297. As I have previously said, Professor Gilmore said in the joint statement (R/40/p. 524-525),

"IG understood JW's wish to bring scientific validity to the question by relying on the confidence intervals of 95% ie the conclusion is likely to be correct 19 times out of 20. In order to achieve that, JW has amalgamated data from other drugs, usually indomethacin, and other routes of administration, such as oral or by injection. However, in IG's opinion this fails to answer the question posed by the court, namely if it finds that diclofenac 100 mg per rectum was not administered and should have been, if it had been administered pre-operatively would the claimant have avoided pancreatitis on the balance of probabilities. ... The test should be that the relative risk (preferably) or odds ratio should be reduced below 0.5. It will be for the court to decide whether or not to deviate from the principle of balance of probabilities and instead take into account the possibility that the balance of probabilities does not reach the 95% confidence limit."

298. In his oral evidence, Professor Gilmore said that he had carried out a 70% confidence interval for the five studies in Lyu and they all came out under 5, i.e. over 50% (transcript 17.03.26, p. 36):

"PROFESSOR GILMORE: But if you take a 70% confidence limit, in other words you'll be right seven times out of ten, the confidence interval goes from about 0.2 to 0.49, so --

JUDGE ROBERTS: Which is what in percentage terms?

PROFESSOR GILMORE: That means seven times out of ten it's correct rather than just the balance of probabilities."

299. In re-examination Professor Gilmore said (transcript 17.03.26, p. 70 – 72),

“MR DUFFY: Yes. I mean, is there -- in terms of statistical difference, is that as relevant in your view for the court, deciding a case on the balance of probabilities, as it would be to the authors of a meta-analysis like this?

PROFESSOR GILMORE: I think if one was submitting to a medical journal, then the statisticians evaluating the study for publication would be looking at confidence intervals, you know, at the 95% level, and I -- in my opinion, that's not the question for the court here, and I think we can give an estimate of more likely than not, which does not breach the 95% level.

MR DUFFY: So in terms of whether a recommendation is going to be made in support of a particular drug, the authors of a paper such as this are not looking at the balance of probabilities. They're looking at a 97% [sic] confidence interval –

...

PROFESSOR GILMORE: And, as I say, the one that I quoted earlier was one where it was -- we could only say it was confident up to the 70% level, seven times out of ten.

MR DUFFY: Just to explain that by reference to the table -- it's page 154 in the bundle and figure 6, I think – so the five studies for diclofenac under rectal routes report a figure of 0.38 as the risk ratio. Do you see that?

PROFESSOR GILMORE: Yes, I do.

...

MR DUFFY: Is that the mean or is that the confidence interval?

PROFESSOR GILMORE: 0.38 is the mean and the --

JUDGE ROBERTS: Sorry, what is the mean? The 0.38?

PROFESSOR GILMORE: The 0.38 is the average, the middle point, and the 0. -- it could be as low as 0.23 or as high as 0.63 with 95% confidence. If you reduce your confidence down to 70%, it comes down to -- I can't remember the lower figure, but the upper figure is 0.49, so you have to reduce your confidence to make it more -- but that's still more likely than not. It's still above the 50% confidence. So that figure I have confidence in, but not confident to the statistical level that I would be looking at if I was reviewing a paper for a journal.”

Finding as to standard of proof and confidence interval

300. I find that the standard of proof in a civil clinical negligence case is the balance of probabilities, namely more than 50%. The standard is not the scientific standard of a confidence interval of 95%. Dr Woodward is applying the standard required to submit a paper to a medical journal. In so doing, he fails to address the question to be answered by the Court of whether the Claimant would have avoided pancreatitis on the balance of probabilities.
301. I note that Mr Cox accepts at paragraph 3(d) of his closing submissions that the crucial issue in this case is “whether administration of rectal Diclofenac is likely to have reduced the risk of pancreatitis by more than 50% in this case”.
302. I accept Professor Gilmore’s evidence that:
- i) The five studies in Lyu et al in which Diclofenac was administered rectally show a risk ratio of 0.38, giving a risk reduction of 62%, and therefore satisfy the balance of probabilities test.
 - ii) The seven studies in table 3s annexed to the European Guideline in which Diclofenac was administered rectally show that the risk ratio or odds ratio was below 0.5 and therefore satisfy the balance of probabilities test.

Conclusion on “but for” causation

303. I find that:
- i) The Claimant must prove causation.
 - ii) The standard of proof is the balance of probabilities, i.e. more than 50%.
 - iii) I reject the Defendants’ contention that this case should be judged by the scientific standard of a confidence interval of 95%.
 - iv) The meta-studies, being medical papers, all consider the issue of the prevention of pancreatitis through the lens of the scientific standard of 95%. I accept Professor Gilmore’s evidence that this is not the enquiry with which the Court is engaged. The Court is tasked with addressing the issue of whether if the Claimant had been administered 100mg Diclofenac rectally, as the Second Defendant intended, his pancreatitis would, on the balance of probabilities, have been avoided.
 - v) Following the guidance of Lady Hale in *Sienkiewicz* (supra), the Court must consider all the evidence when considering causation, including the studies and statistics, and the interpretation put on those studies and statistics by the Consultant Gastroenterologists.
 - vi) Following the guidance of Lord Nicholls in *Gregg v Scott*, “The value of the statistics will of course depend upon ... the closeness of their position to that of the claimant.”

- vii) I find that the Court should consider statistics where Diclofenac was administered rectally because that most closely fits the factual causation in the present case. Further, it is inappropriate to consider the studies involving the administration of NSAIDs orally, intravenously or intramuscularly because it is common ground between all three Consultant Gastroenterologists that those routes of administration are ineffective and only the rectal route is effective.
 - viii) I find that it is inappropriate to consider statistics relating to NSAIDs without distinguishing between Diclofenac and Indomethacin for two reasons. Firstly, Indomethacin is not the factual causation case which is before the Court. Secondly, if one considers the seven studies in table 3s of the European Guideline and the five studies in Lyu et al where Diclofenac and Indomethacin can be compared separately, it can be seen that Diclofenac is more efficacious. I find that the Lyu et al paper shows that in respect of the patients administered rectal Diclofenac, the risk ratio was 0.38, giving a risk reduction of 62%. Using the European Guideline, the seven studies in which Diclofenac was administered rectally show that the risk ratio or odds ratio was below 0.5.
 - ix) I conclude that it is appropriate to rely upon the seven studies in Table 3s of the European Guideline and the five studies in Lyu where Diclofenac was administered rectally as this is the factual causation case which is before the Court.
304. For the aforementioned reasons, I conclude that the Claimant has proved on the balance of probabilities that if he had been administered 100mg Diclofenac pre-operatively rectally, as the Second Defendant intended, it is likely that he would have avoided pancreatitis.

Material contribution

305. In the light of my finding on “but for” causation, it is unnecessary to consider material contribution. However, as I was addressed on it, I set out my findings below.

Law

306. In *Bailey v Ministry of Defence* [2008] EWCA Civ 883 Waller LJ said,
- “46. ... In a case where medical science cannot establish the probability that ‘but for’ an act of negligence the injury would not have happened but can establish that the contribution of the negligent course was more than negligible, the ‘but for’ test is modified, and the claimant will succeed.
47. The instant case involved cumulative causes acting so as to create a weakness and thus the judge in my view applied the right test, and was entitled to reach the conclusion he did.”
307. In *CNZ v Royal Bath Hospitals NHS Foundation Trust & SSHSC* [2023] Med LR 59 Richie J said (authorities bundle/6/p 248),

“391. In law I consider that the cases I have reviewed above show that if there is a scientific gap making proof of causation of functional outcome, therefore also quantification, impossible in contra-distinction to merely difficult, then the Claimant will recover 100% of the damage she had suffered due to the acute PHI so long as the Claimant can prove that the breach made a material contribution to the reduced functional outcome which was more than de-minimis.”

Discussion

308. In a study by Patil and others entitled “Role of Rectal Diclofenac Suppository for Prevention and its Impact on Severity of Post-Endoscopic Retrograde Cholangiopancreatography Pancreatitis in High-Risk Patients” (Gastroenterol Res. 2016;9(2-3): 47-52), it is said,

“Various theories about pathogenesis of post-ERCP pancreatitis have been proposed. But the most accepted theory is mechanical trauma to papilla or pancreatic sphincter causing transient obstruction to outflow of pancreatic juice. ... Regardless of mechanism, the cascade of events is initiated resulting in activation of proteolytic enzymes causing autodigestion of pancreas and impaired acinar secretion. This results in activation of inflammatory cascade causing both local inflammation and systemic effects [5, 6]. The interventions for prevention of post-ERCP pancreatitis aim at breaking this cascade. Non-steroidal anti-inflammatory drugs (NSAIDs) are potent inhibitor of phospholipase A2 which is thought to play a critical role in early inflammatory cascade [7].”

309. Professor Gilmore says in his report, dated September 2025, at paragraph 2.8 (R/31/p. 260),

“It is also thought that an NSAID is likely to reduce the severity of post-ERCP pancreatitis, and so it seems more likely than not that its use would on the balance of probabilities have rendered it less severe if it had not been prevented.”

310. Dr Anderson was asked about the mechanism of post-ERCP pancreatitis (PEP). There was the following exchange (transcript 18.03.26, p. 28-29):

“DR ANDERSON: I’m assuming in this case, because we have no other explanation, that thermal injury from the sphincterotomy --because there is no other explanation -- leads to oedema, swelling, in the adjacent area, which has led to short-term occlusion of the pancreatic duct, which leads to the process of pancreatitis.

MR DUFFY: So it’s the occlusion of the ducts which prevents the escape of secretions from the pancreas?

DR ANDERSON: Yes, and leads to a process of -- pancreatitis is basically auto-digestion of the pancreatic acinar, the cells.

MR DUFFY: The term I used yesterday was 'inflammatory cascade'.

DR ANDERSON: Yes

MR DUFFY: And the diclofenac is designed to -- when applied in an ERCP, it is designed to mitigate the inflammatory cascade. That's right, isn't it?

DR ANDERSON: Yes, I mean, that class of drugs has been known to act in that way and used in rheumatological practice for many, many years and -- so the mechanism action was well known and it's one of several classes of drugs that have been experimented with to try and reduce the incidence of pancreatitis, which is regarded as the gravest downside of this procedure.

MR DUFFY: So where there is an obstruction and an inflammatory cascade occurs, on the balance of probabilities diclofenac will make some contribution to mitigate it?

DR ANDERSON: We believe that that's the mechanism of action, and it clearly does.

MR DUFFY: And that contribution is going to be more than negligible, isn't it?

DR ANDERSON: Well, we didn't know until we did the studies, but we now believe it is clearly more than negligible, yes.

MR DUFFY: There is a further point which relates to severity of pancreatitis, so once it is established how bad it's going to be, and the literature does support a reduction of severity even in cases where pancreatitis isn't avoidable. Do you agree with that?

DR ANDERSON: It reduces severity, I would accept, but in this case the severity was dramatic, terrible, and that is so uncommon that we don't have any literature to guide us at that degree of severity."

Finding as to material contribution

311. I accept the evidence of Professor Gilmore that Diclofenac is (transcript 17.03.26, p. 68),

"An anti-inflammatory and it works by locking the prostaglandins and the interleukins that fuel inflammation, then one would expect it to have an effect, a material effect, but we haven't got the data to show it".

312. Dr Woodward agreed with Professor Gilmore's explanation of how Diclofenac works. He said (transcript 17.03.26, p. 124),

“MR DUFFY: So the diclofenac is designed, isn't it, to interrupt that inflammatory cascade?

DR WOODWARD: Yes. We know that non-steroidals work in that way and we think that's how they reduce the risk of pancreatitis, yes.

MR DUFFY: So in every case where there is such an inflammatory cascade -- well, let me put it like this: where there is an inflammatory cascade, on the balance of probabilities diclofenac makes some contribution to mitigate it, doesn't it?

DR WOODWARD: Yes, one would hope that it would have some effect in terms of the non-steroidals -- diclofenac or indomethacin would have some effect in reducing a degree of inflammation.

MR DUFFY: Yes, and that effect wouldn't be negligible, would it?

DR WOODWARD: Well, not if it's -- if, as we know, these potentially reduce the risk of pancreatitis after ERCP.”

313. Dr Anderson agreed in cross examination that Diclofenac is designed to mitigate the inflammatory cascade (18.03.26, p. 29),

“MR DUFFY: So where there is an obstruction and an inflammatory cascade occurs, on the balance of probabilities diclofenac will make some contribution to mitigate it?

DR ANDERSON: We believe that that's the mechanism of action, and it clearly does.

MR DUFFY: And that contribution is going to be more than negligible, isn't it?

DR ANDERSON: Well, we didn't know until we did the studies, but we now believe it is clearly more than negligible, yes.”

314. In short, the three Consultant Gastroenterologists are in agreement that Diclofenac is on the balance of probabilities likely to have made a contribution that was more than negligible to reduce the inflammatory process which leads to pancreatitis.
315. If I had found that in the case of a patient who was low to medium-risk, there was insufficient data to state on the balance of probabilities whether the administration of Diclofenac rectally pre-procedure would have prevented pancreatitis, I would have found that the Claimant had proved on the balance of probabilities that he suffered a material contribution.

316. I find that the expert evidence of all three consultant gastroenterologists in this case is that on the balance of probabilities:
- i) The contribution of Diclofenac, if given, would have been material and would have reduced the inflammation.
 - ii) That contribution cannot be apportioned between the negligent and non-negligent components.
 - iii) As a consequence of ii) above, the Claimant is entitled to 100% of his damages.
317. Further, for completeness' sake, I find that the following evidence supports my finding that the contribution of Diclofenac, if given, would have been material and would have reduced the inflammation.
318. Firstly, I accept Mr Duffy's submission at paragraph 21 b of his Claimant's Closing Submissions that

“The meta-analyses include data which would support an effect on severity of pancreatitis with administration of Diclofenac which supports a material contribution, even where PEP is not avoided. In Liu [G/65/p. 163-173 at 168] table 2 supports a reduction in severe PEP with RR of 0.45 for Diclofenac and 0.45 overall (all routes all drugs). Individual studies all demonstrate benefit of more than 50%: see Patil for instance”.

319. I note that the subgroup involved all routes of administration and all NSAIDs (Diclofenac, Indomethacin and Other).
320. Secondly, I note that the European Guideline, the American Guideline and the Japanese Society of Hepato-Biliary-Pancreatic Surgery all recommend routine rectal administration of 100mg of Diclofenac or Indomethacin in all cases, whether high, medium or low risk. In cross-examination of Dr Woodward (transcript, 17.03.26, p. 88-89), after referring to the European Guideline and the American Guideline, there was the following exchange:

“MR DUFFY: There was not then a suggestion at this point that NSAIDs should be restricted to high-risk cases, was there?

DR WOODWARD: No, practice had moved on from that by this stage, I would say, and we were now recommending it for all cases --

MR DUFFY: All cases?

DR WOODWARD: -- in -- yes, around this time.

MR DUFFY: All right. I think in Europe the position was from as far back as 2014 to recommend giving in all cases.

That's right, isn't it?

DR WOODWARD: Yes.”

321. The second point above is supported by the paper by Lyu et al, in which it is said (G/64/p. 157-158),

“The definition of risk of ERCP were varied in the included studies. However, we accepted the original author’s classifications. In this study, we found no difference in the incidence of PEP between average-risk and high-risk patients. A similar conclusion has been drawn in the studies of Shen et al. and Patai et al. This conclusion provides the basis for the recommendations of the ESGE and Japanese Society of Hepato-Biliary-Pancreatic Surgery in its guidelines for the prevention of PEP.”

322. Thirdly, in an individual study by Patil and others entitled “Role of Rectal Diclofenac Suppository for Prevention and its Impact on Severity of Post-Endoscopic Retrograde Cholangiopancreatography Pancreatitis in High-Risk Patients” (Gastroenterol Res. 2016;9(2-3): 47-52), it is said,

“Methods: We conducted a single-centre, prospective, open-labelled, randomized trial for evaluating the use of rectal diclofenac in prevention of post-ERCP pancreatitis in high-risk patients. We assessed 526 patients coming for ERCP for different indications. Four hundred patients were eligible for the study. Those not fitting the high-risk criteria and with acute pancreatitis were excluded. These patients were randomized in two groups: 200 patients received rectal diclofenac prior to or during the procedure, while 200 patients received placebos. ...”

...

Conclusion: Rectal diclofenac prior to or during ERCP in high-risk patients reduces the incidence as well as severity of post-ERCP pancreatitis compared to placebo.”

323. Mr Perfect seeks to argue at paragraph 42 of his closing submissions that the Patil paper does not apply because it only applies to patients who are high risk, and a large number of the patients had Sphincter of Oddi dysfunction.
324. I find that the paper does not say its findings are limited to patients who are high risk and have Sphincter of Oddi dysfunction. As I have already found, there is no reason to think that Diclofenac applied rectally pre-procedure would be less efficacious for low to medium-risk patients than for high-risk patients.
325. The Patil paper was not included in table 3s of the European Guideline or in Lyu et al. There is no evidence before the Court as to why it was not included and I find that it is a paper that can be taken into account, although it does no more than confirm a finding that I have already made that the Claimant satisfies on the balance of probabilities the material contribution test.

Conclusion

326. I order that:

- i) There be judgment for the Claimant against the Second Defendant in the sum of £550,000.
- ii) The claim against the First Defendant be dismissed.

Final thoughts

327. This is a very serious case. As a result of Diclofenac not being administered, the Claimant suffered life-threatening severe acute necrotising post ERCP pancreatitis. After the ERCP, the Claimant was in hospital for nearly four months, during which time he underwent multiple operations. He has been left with life-changing consequences with seriously altered bowel function and type 3c diabetes, which has reduced his life expectancy.

328. Firstly, it is concerning that the First Defendant seemed wholly unaware of Regulation 227 of the Human Medicines Regulations 2012/1916, which mandates that a prescription must be in writing. From their witness statements, it would appear that Mr Deppeler, Nurse Mondido and Nurse Ferrari were wholly unaware of this requirement. Mr Deppeler, the First Defendant's Endoscopy Manager, says in his witness statement, dated 10 March 2025 (R/27/p. 229),

“8. ... It is commonplace for a verbal direction to be given by a surgeon to nursing staff to administer Diclofenac as a rectal suppository prior to an ERCP procedure”

329. When it was put to Mr Deppeler in cross-examination that a prescription must be in writing, he agreed. What was conspicuous was his failure to explain why he had allowed it to become commonplace for a verbal direction to be given for prescription drugs which it was known from the outset would be administered, if he knew this was in breach of the law.

330. The Second Defendant repeatedly said in cross-examination that prescriptions were not written in advance. He said (transcript 16.03.26, p. 119),

“We don't give it in advance. We don't -- we give it orally and then we sign for it at the end of the procedure because you don't, until the end of the procedure, know what medications have been given.”

331. The Second Defendant showed no awareness that this was in breach of Regulation 227 of the Human Medicines Regulations 2012/1916.

332. Mr Deppeler said at paragraph 8 of his witness statement (R/27/p. 229) that the failure to record a prescription for Diclofenac in the Drug Prescription and Administration Chart or Short Stay Drug Chart was a “minor recording omission”. Nothing could be further from the truth. If a prescription for Diclofenac had been recorded in the Drug Prescription and Administration Chart, it is likely that Diclofenac would have been

administered and on the balance of probabilities, the Claimant would not have suffered pancreatitis.

333. In this case there were far too many errors in the record keeping, which were wrongly characterised as minor clerical errors or minor recording omissions. They are not minor, they are serious. There was no explanation for them, and the impression given was that the First Defendant considered them to be of no consequence.
334. I am concerned that, notwithstanding the very serious consequences for the Claimant, lessons have not been learned from this case by the First and Second Defendants.