

## THE HIGH COURT

[2016 No. 2033 P.]

BETWEEN

CONCEPTA ANDERSON

PLAINTIFF

AND

LORCAN BIRTHISTLE

DEFENDANT

**JUDGMENT of Mr. Justice Barr delivered on the 20th day of March, 2019****Introduction**

1. This is a medical negligence action brought by the plaintiff against the defendant as representative of the medical and nursing staff at St. James's Hospital, Dublin.

2. The plaintiff was admitted to St. James's Hospital under the care of Dr. Caroline Daly, Consultant Cardiologist, on 15th May, 2014, for the purpose of having a replacement pacemaker inserted. On 17th May, 2014, the plaintiff's permanent pacemaker and lead wires were extracted by Mr. Michael Tolan, Consultant Cardiothoracic Surgeon in St. James's Hospital. Dr. Daly and Mr. Tolan had decided not to insert a temporary pacemaker, also known as a temporary wire, due to the risk of infection. The plaintiff was scheduled to have a new permanent pacemaker implanted in the following days.

3. On 18th May, 2014, the plaintiff had an episode of syncope (meaning a stoppage of her heart leading to a blackout) as a result of which she fell while in the toilet and struck her head against the sink.

4. The plaintiff's case in negligence against the defendant rests on two grounds:-

(a) It is alleged that having regard to the plaintiff's prior history of syncope and falls, there was negligence on the part of Dr. Daly and Mr. Tolan in failing to insert a temporary wire, when her permanent pacemaker was removed on 17th May, 2014.

(b) It is alleged that having regard to the plaintiff's prior history, there was negligence on the part of the medical and nursing staff in the hospital in respect of her postoperative management, for failure to ensure that she was confined to bed and only allowed to ambulate around the ward with assistance. It was further alleged by the plaintiff's experts, that she should not have been placed in a coronary step down ward, as in fact happened, but should have been sent to the Coronary Care Unit post operatively.

5. The defendant denied that there was any negligence on the part of the medical or nursing staff in St. James's Hospital, either as alleged or at all.

**Brief Chronology of Relevant Dates**

08/12/1960 Date of birth of the plaintiff. In her childhood and teenage years she experienced episodes of dizziness and fainting, without any definite diagnosis being made.

03/02/2003 The plaintiff fell in her kitchen due to sudden collapse and loss of consciousness. She was brought by ambulance to Sligo General Hospital. A Holter report of 06/02/2003 showed episodes of complete heart block.

07/02/2003 Letter sent on behalf of Dr. McSearraigh in Sligo General Hospital to Dr. Creane, Consultant Cardiologist, at St. James's Hospital. He is informed that the plaintiff had presented to Sligo General Hospital with collapse and loss of consciousness for one minute. She had had a similar episode six months previously. ECG and brain scan had been normal. A Holter report showed episodes of complete heart block. A request was made that she be treated urgently especially as she was very young and active. A request for a pacemaker was also faxed up with the letter.

11/02/2003 A permanent pacemaker was implanted by Dr. Mulvihill in St. James's Hospital.

27/01/2011 The plaintiff's pacemaker battery was changed by Dr. Caroline Daly in St. James's Hospital.

03/01/2014 The cardiac technician in Sligo General Hospital wrote to Dr. Murray, also in Sligo General Hospital, informing him of a suspected problem with the lead in the plaintiff's pacemaker.

07/01/2014 Dr. Murray writes to Dr. Mulvihill. He forwards the letter to Dr. Daly.

18/02/2014 Dr. Daly directs that the plaintiff should be seen in the OPD with pacing check.

27/02/2014 The plaintiff was seen in OPD by Dr. Daly. She noted the lead warning on the ventricular lead. The plan was for pacemaker lead extraction and a new system to be implanted.

05/03/2014 Dr. Daly writes to Dr. Murray requesting further documentation. On the same date, Dr. Daly writes to Mr. Michael Tolan, informing him of the lead warning on the ventricular lead, with a low impedance and escalating ventricular threshold. She asked him to consider the plaintiff for pacemaker lead extraction. She stated that the intention was to implant a new system on the opposite side. She informed Mr. Tolan "*She is not pacing dependent*".

25/03/2014 Dr. Murray sends Dr. Daly the further documentation that she had requested. Dr. Daly directed that the documents should be added to the plaintiff's notes and should be put on file.

15/05/2014 The plaintiff attends at St. James's Hospital at 10:30hrs. Initially, it is thought that she is for the catheter

lab, however, it is then realised that she is to be admitted for lead extraction by Mr. Tolan. She is formally admitted to St. James's Hospital at 15:41hrs.

16/05/2014 The plaintiff is awaiting surgery. The notes of the cardiology surgical team for that day, state that they discussed the case with Dr. Daly. It was noted that the leads were showing increased impedance. The plaintiff had underlying rhythm. The leads were originally inserted in 2003 and the battery changed in 2011. It was noted that she required a device and lead extraction. It noted "awaiting pacemaker check". It further noted "all ok" and "bloods ok". It noted "discussed with Mr. Tolan - ? for PPM mane".

17/05/2014 The permanent pacemaker and leads were extracted in theatre by Mr. Tolan. A temporary wire was not inserted. Post operatively, the plaintiff was brought to the Robert Adams Ward, circa 12:00hrs. She was given a private room. During the day, the plaintiff walked around the ward. She saw her visitors off at the top of the stairs. She was generally well.

18/05/2014 The plaintiff was generally well during the day. She had a visit from her husband and daughters during the evening. She saw them off from the top of the stairs at 22:00hrs. At 23:18hrs, the plaintiff went to her en-suite toilet. While there, she had a syncope episode lasting six seconds. She fell to the ground and hit her head against the sink. She received treatment for the head wound.

19/05/2014 At 00:30hrs, the plaintiff was transferred to the catheter lab for insertion of a temporary pacing wire. Following this procedure, she was admitted to the Coronary Care Unit.

20/05/2014 A new permanent pacemaker was inserted.

21/05/2014 The plaintiff was discharged from hospital.

### **The Plaintiff's Evidence**

6. The plaintiff is 58 years of age, having been born on 8th December, 1960. She married in 1981. She has three adult daughters and five grandchildren.

7. The plaintiff stated that she had dizziness and fainting episodes during her childhood and teenage years. Investigations carried out were unclear as to the cause of these complaints. She experienced more frequent episodes of dizziness and fainting in the years prior to 2003. She had had some minor injuries as a result of the fainting episodes.

8. On 3rd February, 2003, the plaintiff fainted while in her kitchen and hit her head. She was admitted to Sligo General Hospital under Dr. McSearraigh. The plaintiff stated that she had had a fall in the six months prior to that, while she was engaged in cleaning windows. She had a small bump on her head as a result of that fall. ECG and CT brain scan done in Sligo General Hospital were normal. However, a Holter report dated 6th February, 2003, showed intermittent complete heart block. The plaintiff stated that while she was in the Coronary Care Unit at Sligo General Hospital, she was not allowed out of bed without assistance. She was transferred by ambulance, accompanied by a doctor and a nurse, to St. James's Hospital, where a pacemaker was implanted by Dr. Mulvihill on 11th February, 2003.

9. The plaintiff was seen in St. James's Hospital on a number of occasions subsequently, for unrelated complaints. On 27th January, 2011, the plaintiff came under the care of Dr. Caroline Daly, as Dr. Mulvihill had moved to a different section. She inserted a new battery in the plaintiff's pacemaker on that date.

10. In 2014, when reviewed in the cardiology clinic in Sligo General Hospital, the cardiac technician noticed that there was a problem with one of the wires leading from the pacemaker. The technician wrote to Dr. Murray in the cardiac department of Sligo General Hospital, informing him of the suspected problem with the lead. Dr. Murray wrote to Dr. Mulvihill in St. James's Hospital. He, in turn, referred the letter on to Dr. Daly.

11. On 18th February, 2014, Dr. Daly directed that the plaintiff should attend OPD for a pacing check. She reviewed the plaintiff in OPD on 27th February, 2014. A decision was made that the plaintiff would be admitted to St. James's Hospital for a replacement of her permanent pacemaker.

12. On 15th May, 2014, the plaintiff attended at St. James's Hospital at 10:30hrs. Initially, it was thought that she was going to go to the catheter lab for replacement of the pacemaker. However, it was soon realised that she was for admission, as there was going to be a lead extraction procedure under Mr. Tolan. The plaintiff was formally admitted to the hospital at approximately 15:41hrs.

13. At the time of admission, a falls risk assessment known as "Stratify" was carried out. This was described as being a fairly rudimentary set of questions designed to ascertain if the plaintiff had any mobility problems. The plaintiff was not in any way compromised in terms of her mobility, so she scored zero on the test, meaning that she was fully mobile and was, therefore, not a falls risk.

14. The plaintiff spent 16th May, 2014, awaiting surgery. On the following day, the plaintiff was taken to theatre, where the generator box and the leads were extracted by Mr. Tolan. That procedure was uneventful in itself. A temporary pacemaker was not inserted. It had been planned that the plaintiff would be brought to the Cardiac Care Unit (CCU) postoperatively. However, when there was no bed available in CCU, the plaintiff was sent instead to a cardiac stepdown ward, the Robert Adams Ward. She was given a private room close to the nurse's station. This room had an en-suite toilet. The plaintiff was on telemetry postoperatively.

15. During the rest of that day, 17th May, 2014, the plaintiff was generally well. She was able to walk around her room and in the general ward area. She was visited during the day by her adult daughters. She walked with them to the top of the stairs when they were leaving.

16. A further Stratify falls risk assessment was carried out on 18th May, 2014. The plaintiff again scored zero on that assessment. That evening, the plaintiff received a visit from her husband and daughters. She walked with them to the top of the stairs, when they were leaving at approximately 22:00hrs.

17. Sometime later that evening, at a time that is unclear from the notes, but was probably circa 23:18hrs, the plaintiff went to the

en-suite bathroom to use the toilet. While there, she suffered a syncope episode, causing her to fall to the ground. She struck her head in the area of her forehead, while falling.

18. In her evidence, the plaintiff stated that she had gone to the bathroom to use the toilet. While there, she lost consciousness. She awoke to find herself lying on the floor with two nurses reassuring her that she would be alright. She had a large gash on the left side of her forehead. She was placed on a trolley. The nurses informed her that they would have to notify her next of kin. However, she did not want that due to the late hour.

19. When her head wound had been seen to, she was brought to the catheter lab, where a temporary wire was inserted through a vein in her leg. She was then admitted to the CCU, where she remained until the permanent pacemaker was put in place on Tuesday, 20th May, 2014.

20. It is necessary to deviate from the plaintiff's evidence at this point to deal with the issue of the exact timing of the plaintiff's fall and the sequence of events surrounding that.

21. There was no viva voce evidence on this issue, as the defendant did not call any of the nursing staff to give evidence. Unfortunately, the hospital records are somewhat difficult to reconcile in relation to the exact sequence of events. The plaintiff's telemetry was being monitored in the CCU. Their notes recorded that at 23:18hrs, there was *"ventricular standstill and then loss of leads – contact lost"*. Robert Adams Ward was contacted. It went on to record that the patient had been found in the bathroom. She was unconscious on the floor and had hit her head against the sink. It noted that the leads had come off the patient due to the fall. She had abrasions and swelling to the forehead.

22. The CCU notes go on to record at 23:19hrs *"leads off/junctional Brady"* (meaning Bradycardia). The notes recorded that at 23:20hrs, *"run complete heart block and leads off"*. The timing of the next entry is unfortunately partially illegible. It reads 23.?5hrs, it could be 23:35hrs or 23:45hrs. Portion of the note is also illegible. The legible portion reads as follows:-

*"On arrival to Robert Adams Ward; patient drowsy; blood pressure 170/80; electrocardiogram nil acute and sinus rhythm 80s. Taken to Cath Lab for placement of DPW into the groin, right groin failed attempt. Diazemul 10mg given intravenously."*

23. The rest of the note goes on to document the plaintiff's condition on arrival at CCU, where neurological assessment revealed her to be alert and orientated and moving all extremities. The timing of events in the CCU notes as stated above, is difficult to reconcile with the nursing notes from the Robert Adams Ward, which recorded as follows at 23:45hrs:-

*"Nursed as per care plan. Connie was comfortable early in the night. CCU rang at 23:30hrs and informed that Connie's rate is very low. On checking, Connie was found on the toilet floor. Appeared to have bleeding from the forehead. She was conscious. Brought her back to bed. (as per patient, she did not know what happened in the toilet). Vital signs checked. BPE was high. HR 97. Early warning score 1. ECG taken. As per CCU staff, her rhythm looked like she had 6 seconds of ventricular standstill. Icepack applied to forehead. No further losing. Reviewed by Cardiac SHO. Impression syncope second to AV block. Plan for registrar review. Reviewed by cardiac registrar. Plan – for temporary pacing wire and transfer to CCU. Patient happy with the same."*

24. Thus, it can be seen that there is a discrepancy between the two sets of notes. The CCU notes indicate that Robert Adams Ward was contacted at 23:18hrs. Whereas the nursing notes from that ward, which were made at 23:45hrs, indicate that the call from CCU had been received at the ward at 23:30hrs. Thus, there is a twelve minute discrepancy between the timings given in the two sets of notes. The nurse who found the plaintiff was not called to give evidence, so it is not possible for the court to resolve this discrepancy in the notes. However, this confusion in the notes may not be that relevant, as the plaintiff's cardiology expert, Dr. Cripps, accepted that the plaintiff was probably found by the nurse within seconds of the syncope episode appearing on telemetry.

25. In the course of cross examination, the plaintiff accepted that there was a call bell in her room, by which she could call for assistance from the nursing staff. She further accepted that she had been told that she could use the bell if she required any assistance.

26. It was further put to her that she was informed that she should not go out of the ward, as she had to remain within range of the telemetry, which was being monitored in the CCU. The plaintiff accepted that that was correct. However, other than an instruction to stay within range of the telemetry monitor, she was not restricted in moving about her room, or the general areas of the Robert Adams Ward. The plaintiff's evidence in relation to her injuries will be dealt with later in the judgment.

#### **Other Evidence on Behalf of the Plaintiff**

27. Evidence was given by the plaintiff's husband, Mr. Francis Anderson. He stated that in February 2003, his wife had fallen in the kitchen in their house and had cut her head. He brought her to the A&E Department of Sligo General Hospital. They carried out various tests over the following days, which revealed that she had intermittent heart block. She was in the Coronary Care Unit at that time. While there, she had to remain in bed. When she went to the toilet, there was a nurse behind her, who escorted her to the toilet.

28. In 2014, when her pacemaker had been removed, he visited the plaintiff in hospital. She was in a private room on the Robert Adams Ward. She was in and out of the bed a number of times. She walked him down the corridor when he was leaving. She walked other visitors to the top of the stairs.

#### **Evidence of Dr. Timothy Cripps**

29. On the temporary wire issue, the plaintiff's main liability witness was Dr. Timothy Cripps. He is a consultant cardiologist at Bristol Royal Infirmary, which is a major surgical and teaching hospital in the south west of England. He retired from the NHS in March 2018, but he continues to do private work. His main area of specialisation is in cardiac pacing. He stated that during his career, he has been one of the main consultants in the south west of England for people with pacing problems. He implants a large number of pacemakers each year. He has done hundreds of pacemaker and extraction procedures. His hospital caters for a population of approximately two million. He has treated patients with a very large range of cardiac diseases and conditions.

30. Dr. Cripps was critical of the decision made by Dr. Daly and Mr. Tolan not to insert a temporary wire, following extraction of the plaintiff's permanent pacemaker on 17th May, 2014. He was of the opinion that that decision was inappropriate, because it did not take sufficient account of the plaintiff's significant prior history, particularly prior to insertion of the original pacemaker in 2003. It was highly relevant that according to the notes from Sligo General Hospital, she had had not one, but two, significant syncope episodes leading to falls and injury. It was in those circumstances that the original decision had been made to insert a permanent pacemaker,

which was an entirely correct decision. Thus, it was known at that time that the plaintiff had had episodes of syncope, which had led to falls and injury. Once the pacemaker was inserted, her difficulties with syncope had been resolved.

31. This was highly significant, because it was clearly foreseeable to the doctors that, once her pacemaker was removed, she would revert to her pre-2003 condition, meaning that she was again at risk of syncope episodes leading to falls and possible injury. In these circumstances, he felt that insertion of the temporary wire was clearly mandated.

32. Dr. Cripps stated that in the plaintiff's case, once one removed the pacemaker and did not insert a temporary wire, she was again at risk of having episodes of complete heart block, which carried with it the attendant risks of falls and injury. The fact that she had been put on telemetry postoperatively, did not mitigate that risk. Telemetry merely records the heart rate in real time, it does not prevent a syncope occurring. This was clearly seen in the present case, where the telemetry had revealed that the heart block had lasted for approximately six seconds.

33. Dr. Cripps stated that the insertion of a temporary wire, was a relatively straightforward procedure. It could either be inserted through a vein at the top of the leg, which would be accessed through the groin, or one could use the central line which had been put in place by the anaesthetist. In this case, a central line had been inserted via the plaintiff's neck. Dr. Cripps stated that that could easily have been used for insertion of the temporary wire.

34. Dr. Cripps stated that insertion of a temporary wire for use in the interval between removal of the old pacemaker and implanting of the new pacemaker, was a very common procedure. It is usually done by the cardiologist before the old pacemaker is removed, either in the catheter lab or in theatre.

35. It was put to Dr. Cripps that Dr. Daly and Mr. Tolan, would say that they considered putting in a temporary wire, but, having regard to the fact that she was not pacing dependent, as she only required the pacemaker for 2% of the time, and having regard to the risk of infection caused by insertion of a temporary wire, they had come to the conclusion that it was not appropriate to insert a temporary wire on this occasion. Dr. Cripps accepted that the risk of infection was slightly increased when one inserted a temporary wire. However, the risk of infection caused by use of a temporary wire, remained very low at circa 2%.

36. Dr. Cripps accepted that what was involved was essentially a balancing exercise, with the risk of infection caused by use of a temporary wire, being offset against the risk of the patient having syncope episodes and falls, if she was left without any pacemaker. It was known that she required pacing approximately 2% of the time. This meant that in a 24 hour period, she would require pacing for a total of 28.8 minutes. Given that she had had a syncope episode lasting six seconds at the time of her fall, this meant that there were approximately 288 opportunities for a six second pause in any 24 hours. He felt that this was a significant risk.

37. When balancing the risk of syncope episodes, with the attendant risk of a fall, against the risk of infection, Dr. Cripps felt that in the plaintiff's case, the actual risk of infection was very low. This was due to the fact that the figure given for the risk of infection by use of a temporary wire, was based on literature which had largely looked at older patients, who had comorbidities, such as diabetes and renal failure. There were also other factors which were in the plaintiff's favour. Firstly, she did not have any pre-existing infection or fever. Secondly, she had been given prophylactic antibiotics in advance of the operation. In these circumstances, he felt that the risk of infection by insertion of a temporary wire, was quite low. He thought that it was a much lower risk, than that of leaving the plaintiff without a pacemaker. Accordingly, he was of opinion that a temporary wire should have been inserted.

38. Dr. Cripps accepted that the fact that the plaintiff required pacing 2% of the time, did not mean that she had suffered complete heart block for that entire period. The pacemaker would kick in once the heart rate fell below a set level, usually 60bpm. Thus, there would not have been complete heart block the entire period during which the pacemaker was activated. However, he was of opinion that having regard to the plaintiff's history prior to insertion of the pacemaker in 2003, where she had had two significant falls in the six months prior to February 2003, and where there was a need for pacing for 2% of the time, it was not appropriate to take the risk that she would have such an episode, leading to a fall and possible injury. A patient should not need to have a fall, before deciding to put in a temporary wire. Falls should be avoided if at all possible. If the plaintiff had had a temporary wire in place on 18th May, 2014, she would not have had her fall.

39. Dr. Cripps stated that complete heart block in itself is a serious condition. If the stoppage of the heart is for a prolonged period, there is a risk of death; even if the stoppage is for lesser periods, if there is a fall, that can have serious consequences, because the patient could fracture their skull leading to a cerebral haemorrhage. Thus, the consequences of a fall could be very serious. One had to look not only at the percentage chance of a particular risk happening, but also at the consequences of the risk, if it should come to pass. In this case, the treating doctors knew that the plaintiff had had intermittent complete heart blocks leading to blackouts, falls and injury. They also knew that there was a requirement for pacing 2% of the time; even when weighed against the risk of infection, the use of the temporary wire was clearly mandated.

40. In the course of cross examination, it was put to the witness that the literature which would be relied upon by the defendant's expert, Dr. Quigley, clearly showed that there was a significant risk of infection caused by use of a temporary wire. The main paper referred to by Dr. Quigley was the Klug paper. Dr. Cripps noted that in that study, the infection rate for *de novo* systems, which was arguably applicable in the plaintiff's case, as the new system was implanted in a new pacing site, was 0.56%. While a temporary pacemaker increased the risk by 2.5 times, this still represented a very low risk of  $0.56 \times 2.5 = 1.4\%$ . Even for non *de novo* systems, the risk of infection was only 0.99%, so the increased risk amounted to  $0.99 \times 2.5 = 2.5\%$ .

41. He noted that the multivariate analysis had identified various risk factors for those who had fever in the 24 hours prior to implant, for those who had cutaneous lesions, for situations where there were more than three persons in the operating room, where there was a need for early intervention following implant, for example, for haematoma or lead displacement and also noted an increase in risk of 2.46 where there was insertion of a temporary wire. On the other hand, the risk was reduced by a factor of 0.46 for *de novo* implantation, which was arguably applicable in this case and by a factor of 0.40 for antibiotic prophylaxis. This meant that the plaintiff's overall risk was, therefore, probably less than the average, even despite the risk from the temporary wire.

42. In relation to the other papers mentioned by Dr. Quigley, he felt that the Kosaify paper was not relevant, as it came from Lebanon, and contained a reference to the role of reuse leads contributing to the infection rate; this was not practiced in Europe. He noted that the references given to validate the 10% infection rate, did not seem to contain that data.

43. The McCann paper, although from the UK, was only published in an Indian journal, suggesting that it was not well peer reviewed in the UK. Also, it appeared to take its data, over a very long period, which may not reflect current practice. Nor did it stratify according to risk. It was noted that the complication rate was much lower in specialist centres. In addition, the complication rate in the study included minor complications, such as failure to achieve access, which was the most common complication.

44. The Lopez Ayerbe paper appeared to refer to older patients, who would probably have had co-morbidities. Finally, the paper by Aggarwal showed an infection rate of 2.9% in those with a temporary pacemaker, versus 0.4% in those without. He did not think that that was enough of a risk to contra-indicate pacing in a patient such as the plaintiff, who had no high risk features, such as advanced age, pre-existing infection, comorbidity, or a long duration of temporary pacing. He felt that the conclusion that there was a sevenfold increase in the rate of infection when temporary pacing was used, was misleading, due to the fact that the risk itself remained small.

45. Dr. Cripps was asked what management should have been put in place for the plaintiff, once it was decided not to insert a temporary wire. He stated that if a temporary wire was not going to be used, the plaintiff should have been placed in CCU, with an instruction to the nursing staff that she was to stay in bed on continuous monitoring. She should not have been allowed to ambulate without assistance.

46. In cross examination, it was put to the witness that Dr. Daly would say that, as the plaintiff was in a busy hospital, the risk of infection was quite high. This was even more so when the patient would have visitors and would be examined by medical staff. In such circumstances, there was a far greater risk of infection, than the risk from a syncope episode. Dr. Cripps did not agree. He stated that all hospitals have visitors. In the Klug paper it gave a risk of 2.46%. He did not think that the risk was any higher than that and he thought that in the plaintiff's case, the risk rate was actually lower. The fact that it was a specialist centre of excellence, meant that the hygiene standards would probably have been higher than elsewhere.

47. It was put to the witness that if she had gone on to develop an infection, her life could have been at risk. Dr. Cripps stated that it was possible that if she fell she could have fractured her skull and suffered a cerebral haemorrhage. It was put to him that Dr. Daly had balanced the risk of syncope and blackout, against the risk of infection and in such circumstances her decision had been reasonable. Dr. Cripps disagreed, stating that that decision ignored the fact that the risk of infection from a temporary wire was very low.

48. Dr. Cripps accepted the statement in the paper by Austin *et al* entitled "*Analysis of Pacemaker Malfunction and Complications of Temporary Pacing in the Coronary Care Unit*", that none of the complications looked at had resulted in death. That paper went on to state:-

*"Sepsis, phlebitis and pulmonary embolus were more common with temporary pacemakers in place for 7 hours or longer ( $p = 0.04$ ). Recognition of the problems peculiar to each pacing catheter site and shortening the duration of pacing should help minimize problems with temporary pacing."*

49. However, he stated that a lack of literature did not prove that a particular practice was reasonable. In this case, once the pacemaker was removed, the plaintiff was back in a situation of being at risk of blackout, as she had been prior to 2003.

50. It was put to Dr. Cripps that the McCann paper noted that temporary cardiac pacing wires were usually inserted in an emergency situation. It was a procedure not practiced often, with the average general internal medical doctor in the UK performing less than five per year. It went on to note that complications were common, occurring in 10% to 59.9% of procedures. Dr. Cripps accepted that there were risks with the insertion of a temporary wire. However, the paper went back over the literature over a considerable number of years. It was not the same as the Klug paper. Also it referred to procedures carried out by ordinary doctors, not consultants. He pointed out that for a patient in a centre of excellence, who was under the care of a specialist, they would be at a very low risk, as demonstrated by Figure 2 on p. 44 of the article. He accepted that as the plaintiff was a young woman, she would need a number of pacemakers during her life. However, that did not put her at higher risk of infection.

51. In relation to the mortality rate of 6% given in the Lopez Ayerbe paper, death there was due to heart attack. It was not due to the temporary wire. Furthermore, the level of complications recorded in that paper from that particular hospital, showed that it was not a centre of excellence. He thought that if St. James's Hospital had that level of complications, they would be very disappointed. As a result, he thought that the results in that paper were somewhat of an outlier, insofar as they referred to a clinic that was clearly not performing well.

52. It was put to the witness that in the Klug paper at p. 159, it stated:-

*"The rate of infectious complications in patients who undergo multiple implantations of devices in their lifetime is inordinately high."*

53. Dr. Cripps stated that that did not refer to temporary wires, but to infectious complications from repeated procedures. He cautioned that one would have to be very careful when considering use of a temporary wire in this case. Here, it was warranted because of the plaintiff's history of syncope with head injury.

54. Dr. Cripps was asked about the findings set out in table 4 of the Klug paper, where the adjusted odds ratio for infections caused by a temporary pacing wire were 2.46%. He pointed out that the base level was very low as stated at p. 157, which noted that infections developed over twelve months in 42 patients representing an incident of 0.68 per one hundred patients.

55. Finally, it was put to the witness that in the Aggarwal paper, it was stated at p. 164:-

*"Pacing system removal for infection was, however, significantly more common in patients who had a temporary pacing lead in situ at the time of permanent pacemaker implantation (7 (2.9%) of 242) than in those who did not (3 (0.4%) of 817,  $p = 0.0014$ )."*

56. Dr. Cripps stated that it was still a risk of 2.9%, against a risk of 1%, which was small when put against the risk of the plaintiff falling and hitting her head. He stated that no medical intervention was without risk. It was necessary to weigh up the relative risks and proceed in light of these.

57. In re-examination, Dr. Cripps pointed out that the risk of infection at 2.46% was reduced in this case due to the use of prophylactic antibiotics. That was standard practice now, but was not in use at the time of some of the studies quoted in the papers. Its use caused a significant drop in the risk of infection. Another important factor was whether the patient was already infected at the time that the temporary wire was inserted. That was not applicable in this case. Furthermore, background conditions such as diabetes and renal failure were not applicable in this case.

## **Evidence of Ms. Jayne Mudd**

58. Ms. Jayne Mudd, Nurse Consultant in Cardiac Rhythm Management (CRM), was called on behalf of the plaintiff. Ms. Mudd is based at James Cook University Hospital (JCHU), Middlesbrough, Cleveland, England. She has a Bachelor of Science in Advanced Nursing Practice, as well as two years of study at Masters level. She is currently working towards a doctorate. Aside from her clinical role at JCHU, she has developed a national course for nurses specialising in arrhythmia management. Ms. Mudd has acted as a nurse representative in the Department of Health arrhythmia board in the United Kingdom. She is a trustee of the Atrial Fibrillation Association and an executive member of the Arrhythmia Alliance. In 2013 she was awarded an MBE for her services to health care.

59. Commenting on the nursing care provided to the plaintiff at St. James's Hospital, Ms. Mudd stated that the plaintiff should have been advised to inform nursing staff if she needed to go to the bathroom or elsewhere. There was no documentation in the notes to confirm whether, or not, the plaintiff was advised to do this. The plaintiff had had a history of syncope due to intermittent complete heart block, and therefore Ms. Mudd stated that no reasonable nurse would have allowed the plaintiff to roam freely around the ward without the nursing staff being aware of her whereabouts and observing her closely.

60. Ms. Mudd stated that the plaintiff was nursed on a general ward rather than a Coronary Care Unit, which she asserted would have allowed for closer nursing observation. She was of the opinion that the plaintiff was at risk of collapse and therefore should have been advised by nursing staff to make them aware if she needed to go to the bathroom or elsewhere. It is unclear from the nursing notes if this advice was given to the plaintiff. If this advice was not given, Ms. Mudd stated that that would be a breach of the duty of care.

61. Ms. Mudd was of the opinion that one would have expected a patient without a temporary pacemaker, in similar situation to the plaintiff, to have been nursed in a coronary care environment, or in a monitored bay. This would have allowed for closer monitoring and there would be more nurses to a smaller number of patients. The witness stated that the nurses would therefore not be in a compromised position.

62. Ms. Mudd explained the difference between a Coronary Care Unit and a monitored bay. A Coronary Care Unit is for patients who are acutely unwell with cardiac conditions and require a higher level of monitoring. A monitored bay is a similar environment, but the patients are not as acutely unwell. Nurses are equipped with the same level of expertise and specialist training in both wards.

63. Ms. Mudd accepted that the plaintiff had been in a single room, with its own toilet facilities. She stated that this was not ideal, as the nurses would not be able to see exactly what a patient was doing if they were in a side room. The witness was of the opinion that it would have been better for the plaintiff to be in a bay, as it would have been easier to monitor her.

64. She felt that the general ward on which the plaintiff was nursed was inappropriate, but she accepted that this may have been influenced by bed availability.

65. Ms. Mudd further noted that as the plaintiff did not have a temporary pacemaker in place, she should have been advised to use the buzzer if she needed to go to the bathroom, and that a nurse would have helped with that. Ms. Mudd further commented that she would have expected there to be clear instruction communicated to the plaintiff, as to what to do if she needed to go to the bathroom. She would not have expected the plaintiff to have been allowed to roam freely whilst on telemetry. One would have expected there to be some documentation within the notes, to say that this advice had been communicated to the plaintiff. To her knowledge no such instruction had been given to the plaintiff to notify nursing staff if she wished to leave her bed.

66. It was put to the witness that the plaintiff had been moving around the floor on which she was a patient, and had gone with her family to the top of the stairs, to wave them off. The witness was asked whether this was a safe thing for the plaintiff to be allowed to do, given the particular circumstances. Ms. Mudd answered in the negative. She further commented that there was no clear guidance or instruction given to the nursing staff following the removal of the plaintiff's pacemaker. Ms. Mudd was of the opinion that that was quite important.

67. Ms. Mudd stated that having reviewed the plaintiff's clinical notes and history, there was nothing that indicated to the nursing staff that the plaintiff had already suffered a blackout and fall in 2003. The witness was of the opinion that this information was extremely significant from the point of view of nursing care, as it would have highlighted the risk of the patient suffering another collapse.

68. Ms. Mudd discussed the false reassurance given by the Stratify fall risk assessment tool. She did not think that it was particularly relevant to the plaintiff. Ms. Mudd stated that it was important to use Stratify alongside clinical judgment. The fact that the plaintiff scored a 0 on Stratify, and was therefore deemed safe and not at risk of falls, was futile. She asserted that clinical judgment should have been used and this would have identified that the plaintiff was indeed at risk of collapsing.

69. Ms. Mudd acknowledged that there was a care plan for telemetry monitoring provided for within the nursing notes, but she reiterated that there was no guidance around what the patient should do, if they needed to go to the bathroom. Ms. Mudd was of the opinion that once the increased risk of falling had been identified, another plan should have been put together to manage that risk. She stated that she could not see this in the nursing notes.

70. During cross examination, Ms. Mudd accepted that it was part of the standard patient care plan for the nurses to welcome a patient to the ward, to orientate them in their surroundings, to direct them to the location of the toilets and the nurses' station, to provide the patient with a call bell and show them how to use it.

71. It was put to Ms. Mudd that she was critical in her report of the nursing care. She responded by saying that she was not critical of the nurses per se. She did find, however, that some areas were not well documented, or there was no evidence of whether or not the plaintiff was clearly instructed as to what to do when she needed to go to the bathroom. She further stated that she thought it was the wrong environment in which to nurse the plaintiff and she believed that the nurses had been put in a difficult position because of that.

72. It was put to Ms. Mudd that the ward the plaintiff was in was as close to a monitored bay as you could get, in the circumstances. The plaintiff was under telemetry, there were cardiac nurses available, and she was only steps away from the nurses station. Ms. Mudd was of the opinion that given these facts, she would question even more so as to why the plaintiff was allowed to mobilise freely.

73. It was put to the witness under cross examination that even if a nurse had accompanied the plaintiff to the toilet, she would have collapsed in the same way. Ms. Mudd responded by saying that in her hospital they would have taken a patient, in a similar situation to the plaintiff, to the toilet in a wheelchair.

74. Ms. Mudd finished giving evidence by saying that she did not believe that it was the nurses decision to put the plaintiff on that particular ward, and that it was not their decision not to put in a temporary wire.

#### **Evidence of Dr. Caroline Daly**

75. Dr. Caroline Daly qualified as a doctor in 1995. Having done her initial training in Tallaght Hospital, she did her Ph.D. in Imperial College in London in 2003/2004. She was involved in writing the guidelines on the management of stable angina, which are used throughout Europe. She did an advanced fellowship in Boston for one year. She has been a consultant cardiologist in St. James's Hospital since 2010.

76. Dr. Mulvihill had implanted the plaintiff's first pacemaker in 2003. Dr. Daly had taken over from Professor Walsh in 2010. In 2011, she changed the generator in the plaintiff's pacemaker. This was done in the catheter laboratory. Thereafter, the plaintiff continued to have regular pacing checks in Sligo General Hospital. She was aware that the plaintiff had had syncope, caused by intermittent complete heart block. She was also aware that the plaintiff was not pacing dependent, as she only needed the pacemaker approximately two percent of the time. She was also aware that the plaintiff was on medication.

77. Dr. Daly was aware of the initial letter sent by a member of Dr. MacSearraigh's team in Sligo General Hospital to Dr. Creane at St. James's Hospital on 7th February, 2003. She was also aware of the Holter report and scan which had been faxed up with that letter. On the Holter report there was a handwritten note to the effect that the plaintiff had complete heart block and needed a pacer (PPM). That had been written in by Dr. Creane in Saint James's Hospital.

78. Dr. Daly stated that from this documentation she had been aware that the plaintiff had had two collapses during the six months preceding her admission to Sligo General Hospital in February 2003. That letter had stated that the plaintiff had presented with a history of collapse and loss of consciousness for one minute. It noted that she had had a similar episode six months previously. There had been no other episodes of loss of consciousness, or collapse within the preceding six months. The plaintiff's general health appeared to be quite good.

79. Dr. Daly stated that she first met the plaintiff in 2011, when she had been admitted on 27th January 2011 for a pacemaker box change. The leads from her pacemaker appeared to be working well at that time, so they were not replaced. This procedure had been uneventful. Dr. Daly wrote to the plaintiff's GP on 18th April, 2011 informing him of the procedure and further informing him that the plaintiff would undergo follow up and pacing checks in Sligo General Hospital.

80. The next significant document was the letter from the Cardiac Technician, Ms. Frain to Dr. Murray in Sligo General Hospital on 3rd January, 2014. That letter informed him of a problem with the leads from the pacemaker. In the letter the technician had noted that the plaintiff was not pacemaker dependent and was paced less than two percent, with a sinus rhythm of 60 bpm. The plaintiff's sinus rhythm was a little low, but she was on medication to slow her heartbeat. By stating that pacing was less than two percent, this meant that the pacemaker was not required ninety-eight percent of the time. That can be ascertained from interrogation of the pacemaker.

81. The letter that was sent by Dr. Murray to Dr. Mulvihill on 7th January, 2014. It was forwarded by Dr. Mulvihill to Dr. Daly. She directed that the plaintiff should be seen in OPD with a pacing check. She asked for that to be carried out "soon".

82. Dr. Daly saw the plaintiff in OPD on 27th February, 2014. The problem on the ventricular lead was noted. The plan was for a pacemaker lead extraction and insertion of a new system.

83. On 5th March, 2014, Dr. Daly wrote two letters. The first was to Dr. Murray in Sligo General Hospital, requesting him to forward the echo reports and correspondence concerning the plaintiff's medication. That documentation was subsequently received on 25th March, 2014, at which time Dr. Daly requested that the documents be added to the plaintiff's notes and placed on file.

84. The second letter written on 5th March, 2014 was sent to Mr. Michael Tolan, Consultant Cardiothoracic Surgeon at Sligo General Hospital. She informed him of the problem with the ventricular lead. She asked him to consider the plaintiff for a pacemaker lead extraction and there would be subsequent implantation of a new system on the opposite side. The letter ended by stating that the plaintiff was "not pacing dependant". Dr. Daly stated that she had decided to ask Mr. Tolan to take out the leads, as she felt that as they had been in-situ for a considerable period, they could be a source of infection. Accordingly, she had decided to remove the pacemaker and the wires. These would be replaced some days after the extraction. Dr. Daly stated that by telling Mr. Tolan that the plaintiff was not pacing dependant, she was telling him that the plaintiff would not need a temporary pacemaker.

85. Dr. Daly stated that she had made a considered decision in the circumstances not to insert a temporary wire. She made this decision in what she perceived to be the best interests of the patient. She made that decision because there was a significant risk of infection with insertion of a temporary wire, which varied depending on the access route. Access via the jugular vein was cleaner, whereas access via the femoral vein was more dirty. The subclavian vein was not available on this occasion, as they wanted that site for the permanent leads. Also, the fact that the plaintiff had a lead in situ on the right meant that if there was a problem on the left side of the heart, they would have to go in via the abdomen, which was less suitable.

86. Dr. Daly stated that because a temporary wire would breach the skin of the patient, that could be a means of introducing bacteria directly into the blood supply, which could be brought to every part of the body and in particular, to the heart. The temporary wire could acquire bacteria from the air, from peoples' hands and from the patient's skin. The wire acts as a pathway directly to the heart. For this reason, any infection can have serious consequences for the patient. Dr. Daly explained that the tip of the wire would be in the right ventricle in the heart, with the wire coming out the femoral vein. It would be secured by tape to the skin and then attached to a generator box which would be on a stand similar to a drip stand. The generator would be interrogated frequently. This would enable bacteria on the generator to track down the lead and go into the blood system and into the heart. In a busy hospital there was a large incidence of infection, due to the fact that there would be a lot of ill people in the same place. All the beds in St. James's were in use, so the frequency of infection would be higher.

87. In relation to the decision in this case, Dr. Daly stated that it was relevant to note that the plaintiff had only had two episodes of syncope in the six months prior to her admission to Sligo General Hospital. The frequency of syncope and the fact that she had intermittent complete heart block was relevant.

88. Dr. Daly stated that generally, 50% of patients undergoing lead extraction, would require a temporary wire. She estimated that in St. James's Hospital three/four temporary wires would be inserted per week. That would equate to circa. 200 per annum. While she accepted that it was a procedure that was frequently done, she maintained that a temporary wire would only be inserted where it was absolutely necessary.

89. Dr. Daly stated that there were also other risks involved in using a temporary wire, in particular as it was a blind procedure which had to be done under x-ray. This carried a risk of puncture to the femoral vein, or adjacent nerves. It was also possible to puncture the lung, or the carotid artery, or it was possible to perforate the right ventricle in the heart. That would be a very serious issue. It can cause tapenade, which can be fatal. She accepted that perforation was infrequent. However, while the percentage of patients suffering that complication was small, the consequences were huge. They could be fatal.
90. Dr. Daly stated that when she had worked in the United Kingdom she had experience of one patient, who had come into hospital with complete heart block. Postoperatively he developed infection due to the insertion of a temporary wire. He subsequently died from that infection.
91. Dr. Daly stated that even in the light of the events which had transpired, she still thought that her decision not to insert a temporary wire, was justified in this case. She would not change her view simply because the plaintiff had banged her head. The relevant factors for consideration, were the risk of infection, as against the risk of the plaintiff having syncope and a fall in the few days between extraction of the old pacemaker and insertion of the new one. She reiterated that her decision not to use a temporary wire had been a considered decision, which she had made in the best interests of her patient.
92. In relation to the plaintiff's postoperative management, she stated that it had been her intention that the plaintiff would go to the CCU. However, St. James's was a very busy hospital, as it was a centre of excellence for cardiac care, and therefore it was sometimes not possible to guarantee a bed in CCU at any given time. When there had been no bed available for the plaintiff after her operation, she had been admitted to the cardiac stepdown ward, which was one floor up from the CCU. The plaintiff was on continuous telemetry postoperatively, which was being monitored on a twenty-four-hour basis in the CCU. They had a "hotline" telephone, with which they could communicate directly with the Robert Adams Ward, if anything showed up on telemetry. Dr. Daly stated that she was not concerned when the plaintiff was in the Robert Adams Ward on telemetry.
93. Dr. Daly stated that when the plaintiff was on the Robert Adams Ward after removal of her pacemaker, she was completely well. She did not have any rhythm problems. Even had she been in the CCU, she would have been allowed to go to the toilet unsupervised. She would have been allowed walk around. Generally, a nurse would not go into a toilet with a patient, when the patient was perfectly well. She did not think that it was necessary for the plaintiff to be brought in a wheelchair to the toilet when she was perfectly well and had had thirty-six hours of good sinus rhythm.
94. She still thought that the risk of long term complaints caused by infection through the temporary wire, outweighed the risk of the plaintiff having syncope and a fall. She had weighed up the evidence, which had revealed that there was a significantly higher risk of infection in patients when they were on their second pacemaker. To double the risk by putting in a temporary wire, would not have been justified.
95. Dr. Daly accepted that it was quite easy to insert a temporary wire. She had not put one in because she did not think that it was the right thing to do. The guidelines and general practice were that a temporary wire would only be put in when it was absolutely necessary. This was usually done where there was a high dependency on pacing.
96. In cross-examination, the defendant stated that she had dealt with cases of intermittent complete heart block previously. She accepted that if a patient did not have a pacemaker, there could be transient complete stoppages of the heart. She accepted that the extent to which a person's heart would restart after such a stoppage, was not known for certain. In this case the plaintiff's heart had restarted quickly without any intervention. That was the most common outcome. However, she accepted that it was not the guaranteed outcome. Dr. Daly did not accept that mortality would be a significant risk, once the patient was in a hospital under telemetry. In such circumstances, her heart rate was under constant observation. Even when it dropped, there were experienced nurses on hand to deal with the matter. Once a patient was in a hospital, it was easier to restart the heart if it should stop, than it would be to stitch a hole in the heart caused by insertion of a temporary wire, or to treat an infection in the heart caused by such a wire. She stated that the guidelines issued in 2017 advised that a temporary wire should only be inserted when it was absolutely necessary.
97. Dr. Daly accepted that the plaintiff was young when she was diagnosed as needing a pacemaker in 2003. She accepted that she would need a number of pacemakers in the course of her life. She accepted that putting in a pacemaker itself carried a risk of infection. However, she felt that inserting a temporary wire would only double the risk of infection and one would try to avoid that, if possible.
98. Dr. Daly was asked about the rate of infection from temporary pacemakers in St. James's hospital. She stated that she was unable to give a precise figure, as she had not audited the rate of infection from temporary wires. However, she was aware of a number of patients in the hospital who had been infected in that way. She would not like to guess at the total number. However, she was able to think of two patients, who had been infected in the previous three years. She accepted that those patients had had a preceding infection.
99. In relation to the decision which she had made, she accepted that when making such a decision it had to be patient specific. However she was aware that the plaintiff was reasonably young and was generally healthy. She was aware that she had a two percent pacing dependency, and that her sinus rhythm was 60 bpm.
100. Dr. Daly accepted that on 5th March, 2014 she had asked Dr. Murray for more information in relation to the echo cardiogram and in relation to her history and her medications. However, she felt that she had sufficient information before her to make the decision that a temporary wire was not necessary, because it was clear that the plaintiff was not pacing dependent. She had told Mr. Tolan in a letter of the same date that the plaintiff was not pacing dependent. She had also discussed the case with him, or with a member of his team. She recalled receiving a call from a member of his team, informing her that the cardiothoracic team wanted to know whether the plaintiff would need a temporary wire and she had responded in the negative.
101. Dr. Daly stated that in the notes for 16th May, 2014, it was recorded that she had had a discussion with the senior registrar on Mr. Tolan's team. She recalled a telephone call in which it was decided that the plaintiff would need a pacing check and if she had a low level of pacing, she would not require a temporary wire, but would require monitoring on telemetry. She stated that it would have been her responsibility to insert the temporary wire, if one was going to be put in.
102. In relation to her conversations with the plaintiff, she had met the plaintiff on the day of her admission to the hospital. She had told the plaintiff that the pacemaker would be removed and that a new pacemaker would be inserted a day or two later. She did not recall discussing any specific risks that may arise in the days between removal of the old pacemaker and insertion of the new one.



103. Dr. Daly accepted that after removal of the pacemaker, the plaintiff would revert to her pre-March 2003 cardiac condition. Monitoring showed that it was a non-progressive condition, so she reverted to the 2003 position. She accepted that the 2003 position was that the plaintiff had had a collapse, leading to a head injury, necessitating her admission to Sligo General Hospital. The letter also noted that she had had a similar episode six months earlier. The Holter report showed that she had intermittent complete heart block, with pauses of three and six seconds. Dr. Daly accepted that she was aware of those matters when making her decision. She also accepted that the absence of a pacemaker, did alter the plaintiff's risk of heart stoppage and potential fall. It was that possibility which was realised in the incident on 18th May, 2014. She accepted that the consequences of a blackout and/or fall, could vary depending on the location where it occurred.

104. It was put to the witness that no direction had been given to the plaintiff to follow any particular regime, given that she had no pacemaker and was therefore at a risk of falling. Dr. Daly stated that when the telemetry was fitted, she was advised not to leave the ward and to advise nursing staff if she was moving between bays in the ward. It was further put to the witness that the nurses were not advised that the plaintiff should be confined to bed and that they should be notified if the plaintiff wished to go to the toilet. Nor was any direction given to the nurses that the plaintiff should not ambulate without assistance. Dr. Daly accepted that she had not seen any such directions recorded in the notes. It was put to her, that she had not given any such directions. Dr. Daly agreed, but stated that on the ward round which she had conducted, the senior nurse was aware that the plaintiff had had her pacemaker removed and was being monitored because of a risk of falling. It was for that reason that she had been put in a room closest to the nurses' station. In addition, the senior nurse would attend the ward rounds, where they would discuss the patient's individual care needs, such as the requirement for telemetry and how best to monitor her.

105. It was put to Dr. Daly that the plaintiff had had blackouts and falls on previous occasions, prior to having her pacemaker inserted, but that was not known to the nursing staff on Robert Adams Ward. Dr. Daly accepted that the nurses would not have been aware of those facts unless told of them. She also confirmed that she had not given any instruction to the nurses that they should attend the bathroom with the plaintiff. Dr. Daly stated that the plaintiff's history revealed that her episodes of complete heart block, was an intermittent problem, which only occurred very infrequently. However, she accepted that a pacemaker had been inserted, because one would not know when the heart would stop. That was why it was put in permanently.

106. Dr. Daly accepted that if there was no temporary pacemaker inserted, there should be additional supervision of the patient. That had been catered for by monitoring her heart rhythm by telemetry. It was put to the witness that if a patient had a history of falls and was at a risk of falls due to the absence of a temporary wire, they should be kept in bed. The defendant disagreed with that assertion. They do not direct that patients should always stay in bed. Once on telemetry, they may be allowed to sit beside the bed and even to ambulate. The plaintiff had been instructed that she was not to leave the ward given the range of the telemetry monitor. She was also told to let the nurses know where she was at all times. Dr. Daly accepted that the plaintiff was allowed to walk around the ward and to walk on the corridor.

107. It was put to Dr. Daly that the plaintiff had not been told of the risk of falling due to the removal of her pacemaker. The defendant stated that they had identified the plaintiff as a young and intelligent patient, who understood that her pacemaker had been removed. She also understood that the pacemaker had originally been put in due to syncope and that there would be a temporary period when she was without a pacemaker. It was put to the witness that the plaintiff was not told that she might fall, if she should go to the toilet unaccompanied. Dr. Daly agreed with that statement, but pointed out that the plaintiff had gone to the toilet on other occasions without falling.

108. In re-examination, Dr. Daly stated that she had not refrained from putting in a temporary wire on any grounds of convenience. She had made a decision not to put one in, having regard to the risk of infection that it posed. She pointed out that if she had put in a temporary wire and if the plaintiff had gone on to have an infection as a result of that with serious, and possibly lifelong consequences, she would have had to have explained why she had taken that course when it was not absolutely necessary. She was satisfied that she had done what she thought was in the best interests of her patient.

109. Dr. Daly stated that from her knowledge of other hospitals, she was aware that they do not put in temporary wires unless it is absolutely necessary. She pointed out that no temporary wire had been inserted when the plaintiff was admitted to Sligo General Hospital in 2003.

110. Dr. Daly was asked whether it was necessary to advise the nurses that the plaintiff should be required to remain in bed. Dr. Daly stated that she did not consider it necessary for the plaintiff to remain in bed. If she had had frequent pauses on monitoring, that advice might be necessary. However, the plaintiff was perfectly well and was on constant monitoring on telemetry. The plaintiff had only one risk factor for falls. There were other factors such as mobility or cognitive issues generally, which were not relevant in this case.

#### **Evidence of Mr. Michael Tolan**

111. Mr. Michael Tolan was called to give evidence on behalf of the defendant. He is a Consultant Cardiac Surgeon in St. James's Hospital and in St. Vincent's Hospital. He was appointed a consultant in 1999. He performs adult cardiac and thoracic surgery. He manages the lead extraction unit, which deals with the pacemaker procedures in Ireland.

112. Mr. Tolan was the cardiac surgeon who removed the plaintiff's pacemaker. He briefly explained to the court this procedure. It is done using a very specialized laser, and the procedure can take anything between 30 minutes – 2½ hours. He explained how removing the pacing wires from the veins can be very dangerous.

113. It was put to Mr. Tolan that Dr. Cripps was critical of how Mr. Tolan and his surgical team had not inserted a temporary wire before extracting the plaintiff's pacemaker. Mr. Tolan responded by saying that there are circumstances when it is appropriate to elect to not insert a temporary wire. He stated that the decision is made jointly between his cardiothoracic surgical team and Dr. Daly's treating cardiology team.

114. Mr. Tolan stated that in approximately 50% of cases, the decision is made to not insert a temporary wire. During his time working at St. James's Hospital, performing these procedures, Mr. Tolan stated that his team have never once regretted a decision to not insert a temporary wire.

115. When making a decision to use a temporary wire or not, Mr. Tolan explained that one has to assess the risks, and then balance the consequences of these risks. He stated that in a situation where there was an extremely low dependency on pacing, one would elect not to use a temporary wire.

116. It was put to the witness that Dr. Cripps had asserted that in circumstances where a patient was at risk of collapsing or falling,

a temporary wire was necessary. The witness rejected this assertion, and said that it was appropriate to balance the risk of collapsing with other risks, such as infection.

117. Mr. Tolan was asked about the risk of infection, and what can happen if an infection gets into the system. He explained how an infection can begin at the cardiology ward when the pacing wire is put in. Mr. Tolan commented on inserting the wire via the groin, stating that it was an area that was prone to bugs and infection. Mr. Tolan also stated that the abdomen was not an ideal location to insert the wires.

118. It was put to Mr. Tolan that Dr. Cripps was of the view that when this procedure was carried out in a sterile environment, the risk of infection was negligible. Mr. Tolan stated, however, that although the risk was numerically negligible, the consequences of the risk were quite significant. Mr. Tolan was of the opinion, however, that the plaintiff was at high risk of infection, as it was her second pacemaker procedure.

119. Regarding the availability of beds in the Coronary Care Unit, Mr. Tolan stated that a bed could not be guaranteed. When no CCU beds were available, incoming patients go to the Robert Adams Ward, where they are monitored on telemetry. He commented that the nurses on the Robert Adams Ward are highly skilled and all the patients are closely monitored.

120. It was put to Mr. Tolan that Dr. Cripps was critical of the decision not to put in a temporary wire, in circumstances where the plaintiff presented with a risk of syncope. Mr. Tolan said that given the level of pacing the plaintiff required, and given that it was an extremely low dependency, he had no doubt that the plaintiff did not need a temporary wire.

121. Under cross-examination, Mr. Tolan stated that as a cardiac surgeon, all he needed to know was whether a patient was pacing dependent or not. Explaining the term "pacing dependency", Mr. Tolan said that when a person's heart does not beat without pacing, they are known to be 100% pacing dependent. The plaintiff had a 2% requirement for intervention by the pacemaker, some of which, Mr. Tolan explained, was due to a low heartbeat when asleep, and at other times it was attributable to her underlying congenital heart condition.

122. The plaintiff's syncope occurred when she was going to the toilet. It was put to Mr. Tolan that prior to this, the plaintiff had mobilised around the ward and had gone to the top of the stairs, where she had bid her family goodbye. He agreed that that was correct. He also agreed that this syncope may not have happened if a temporary pacing wire had been in place. He further stated, however, that in an ideal situation, where there were no risks to temporary wires, everybody with a heart conditions would have a temporary wire put in. However there were risks and the risks had to be balanced, as was done in this case.

123. In light of evidence given by Dr. Daly, a question arose during the course of cross-examination regarding internal communication between this witness's surgical team and Dr. Daly's medical team. Mr. Tolan had stated in evidence that he had discussed temporary pacing with Dr. Daly prior to the plaintiff's procedure. However, during cross-examination it was put to the witness that Dr. Daly had indicated that the discussion regarding temporary pacing of the plaintiff was not a communication which she had had personally with Mr. Tolan, but with a member of his team. Mr. Tolan agreed with that assertion.

124. During cross-examination however, Mr. Tolan rejected the assertion that he had proceeded in the absence of any discussion with Dr. Daly regarding the insertion of a temporary wire. He stated that there was full and adequate discussion between the two teams, that should be regarded as reasonable in a busy hospital, including a letter from Dr. Daly to the witness dated 5th March, 2014, which had stated that the plaintiff was not pacemaker dependant, and a further phone call on the 16th May, 2014, the day prior to the operation, to clarify this position, before the wires were cut.

125. Mr. Tolan confirmed that as long as he has received a communication from the cardiologist that a patient was not pacing dependant, and subject to clarifying that prior to the operation, he would proceed on the basis that a temporary pacing wire was not necessary.

126. Regarding the risk of infection when inserting a temporary wire, under cross-examination Mr. Tolan stated that it may be a small risk, but the consequences could be catastrophic.

## **Other Evidence on Behalf of the Defendant**

### **Dr. Peter Quigley**

127. Dr. Peter Quigley was called on behalf of the defendant. Dr. Quigley is a Consultant Cardiologist. He qualified from Trinity College Dublin in 1976 and completed his internship in the Royal City of Dublin Hospital, where he also began to specialise in cardiology. In 1984 he went to Kings College Hospital in London to work as a registrar in cardiology, where he did research and clinical work for two years. He then went to Duke University Medical Centre in 1986, where he spent three years specialising in coronary interventions, angioplasty and stenting. He subsequently began working in St. Vincent's University Hospital until 2014, and now works exclusively at St. Vincent's Private Hospital.

128. Dr. Quigley noted that the plaintiff's most recent pacemaker check had indicated that she was not pacemaker dependant and only required pacemaker function 2% of the time. He interpreted the 2% dependency to mean that, when the plaintiff was having a new system put it, it was safe to leave her without a temporary pacemaker for a few days, as this avoided the potentially long term life morbidity or even mortality, which can be associated with subsequent infections of such systems. He stated that this risk of infection surmounted any other risk, and therefore minimising the risk of infection was paramount.

129. Dr. Quigley stated that it appeared most likely that the plaintiff's collapse and subsequent injury was due to a transient period of low blood pressure brought on by a sudden dropping of the heart rate.

130. Dr. Quigley reviewed the plaintiff's hospital notes and correspondence between the plaintiff's GP, referring consultants and cardiothoracic surgery team. He was satisfied that there was sufficient documentation of the patient's medical history, with appropriate dialogue between doctors. He was of the opinion that not putting in a temporary wire amounted to a considered decision on the part of the consultant medical team, a decision with which he fully concurred. When asked to expand on this, he stated that Dr. Daly and Mr. Tolan would have both been aware of the potential complications of putting in a temporary wire, and that it was not a trivial procedure, as Dr. Cripps had suggested. It was not a completely benign procedure and there could be serious adverse effects

131. Dr. Quigley referred to the study by Klug *et al.*. This was a major study carried out on 6,319 patients, which looked at the use of temporary pacing wires prior to the implantation procedure of a permanent pacemaker. That study found an overall infection rate of 0.56% for *de novo* implantations and 0.99% for non-*de novo* implantations. This clearly showed that the insertion of a temporary wire

increased the risk of infection by 2.5 fold. According to Dr. Quigley, the Klug paper revealed that in the case of a non-*de novo* implantation, the risk of infection could be higher. Thus, if the decision had been made to insert a temporary wire in the plaintiff's case, that would have given her a 2.5% chance of developing an infected pacemaker within a year of the procedure. Dr. Quigley stated that it was not the immediate risk of infection that represented the major concern in the plaintiff's case, but rather the risk that placing a temporary wire prior to the insertion of a new pacemaker would predispose the plaintiff to an increased risk of infection with the new system, in the weeks or months following the procedure. According to Dr. Quigley, the rate of infection can rise to as high as 12.6% depending on the literature one referred to. It would also depend on the culture of individual hospitals.

132. Dr. Quigley stated in evidence that according to Klug's paper, patients who undergo multiple implantations of devices, like the plaintiff, have an inordinately high rate of infectious complications.

133. It was put to Dr. Quigley that the risk of infection elicited from the literature was an acceptable level of risk, when placed against the idea that a person might be left unpaced and in circumstances where they may fall or collapse and suffer injury. Dr. Quigley disagreed with this assertion and said it was not an acceptable level of risk.

134. Dr. Quigley stated that using a telemetry monitoring system was considered the normal standard of care. He considered it reasonable, under the circumstances described, to allow the patient to go to the toilet unaccompanied. He stated that he did not think that hospital staff would normally go into a toilet with a patient. He was of the opinion that even if the plaintiff had been accompanied, it would not have guaranteed that such an event would not have happened. Dr. Quigley was asked what would have happened if the plaintiff was in the Coronary Care Unit and required to go to the bathroom. He stated that they would have allowed her to go to the bathroom. He thought it would be reasonable in this situation where the plaintiff had such a low likelihood of having a fall, to allow her that freedom and dignity. Ms. Mudd's suggestion that the plaintiff should have been put into a wheelchair or commode and wheeled to the toilet was put to Dr. Quigley. He stated that he has never seen that sort of practice being done.

135. Dr. Quigley stated that the plaintiff had no mobility problems and he did not see it unreasonable to allow her mobilise freely. He was of the opinion that she was in a specialised step down ward, with experienced nurses who were well equipped to look after patients who have come back from these types of procedures.

136. When asked about the criticisms levelled at Dr. Daly, for failure to highlight in the plaintiff's notes issues in relation to the potential of falling, Dr. Quigley stated that he was absolutely convinced that Dr. Daly would have spoken about the situation with a nurse, who was on the ward round with her. The fact that it was not in the plaintiff's notes was not unusual, as they do not record everything that they talk about on the ward.

137. Dr. Quigley stated that the avoidance or minimization of the use of temporary pacing was the recommended standard of care, when managing patients who required a permanent pacemaker. This was stated in the Heart Rhythm Society expert consensus statement from 2017. Dr. Cripps had dismissed this document as it was post event. Dr. Quigley asserted, however, that the guidelines in the paper were a product of many years accumulation of data, which would have reflected best practice in 2014.

138. Dr. Quigley stated that when you have established a patient's need for a pacemaker, you would advise a patient to stop driving, not to climb a ladder, not to do any work on a roof and not to swim. He stated that you would advise a patient in this situation to not do anything that might compromise them should they have a dizzy spell or a blackout.

#### **Ms. Paula McCarthy**

139. Ms. Paula McCarthy was called to give expert nursing evidence on behalf of the defendant. Ms. McCarthy qualified as a nurse over 30 years ago. She has extensive hospital experience, having worked in the Royal Victoria Eye and Ear Hospital, Dublin and in St. Vincent's University Hospital and St. Vincent's Private Hospital, Dublin. She stated that she had a wide range of experience across a range of disciplines, including extensive experience in cardiology. She has worked at all levels within hospitals, from bedside to senior management level. In 2018, she completed a course looking at international best practice in falls risk management, to reduce the risk of people falling primarily in the acute hospital setting.

140. Ms. McCarthy stated that the plaintiff had been assessed in respect of falls risk under the Stratify Falls Risk Assessment Tool, both at the time of admission and again on 18th May, 2014. On both occasions, she had achieved a zero score, meaning that she was not deemed to be at risk of falling. She had also been provided with a call bell in her room and had been instructed how to use it, should she require assistance from a nurse.

141. Ms. McCarthy stated that from the hospital records, it was seen that care plans had been put in place to deal with the plaintiff's care at various stages during her stay in hospital. The purpose of these care plans was to maintain a safe environment for the patient at all times. There was also a telemetry care plan, which had been put in place because the plaintiff did not have any pacemaker in situ after the old one had been removed on 17th May, 2014. Accordingly, it was necessary that she be closely monitored. This was done by ensuring that she was on continuous telemetry, which would be observed by a nurse in the monitoring station in the CCU.

142. Ms. McCarthy stated that all details may not be documented in a patient's notes. The doctor would have told the nurses that the pacemaker had been removed and that she needed cardiac monitoring, which had been put in place and in addition, she had been given a room nearest the nurses' station in Robert Adams Ward. That was a step down cardiac ward, which would be staffed by very experienced cardiac nurses. The nurses would be told that the patient was on a telemetry monitor, they would be informed what her condition was and what consultant she was under.

143. It was put to the witness that the plaintiff's expert, Ms. Mudd, had been critical of the lack of directions given by Dr. Daly to the nursing staff. Ms. McCarthy stated that the nurses needed accurate information to enable them to look after the patient. They are able to see all the clinical notes on her file and so were able to get a full picture of her medical condition during her stay in hospital. In addition, there would have been communication between the doctors and the nurses who were providing care, some communications may not have been written into the notes. This would arise when patients first came onto the ward and when a patient came back from theatre. The doctors would visit the patients on the ward and would inform the nurses of the up to date position. The doctors and nurses would be aware of the care plans and have an input into their development throughout the patient's stay in hospital.

144. Ms. McCarthy did not accept the criticism made by Ms. Mudd that the plaintiff's condition was not properly recorded and that she needed extra monitoring. It had been recorded in her notes that the plaintiff had a history of AV block, so the nurses would have known that the plaintiff was at risk of syncope and of falling. They were also aware that she did not have a pacing device in situ. The nurses had sufficient information to allow them to appropriately manage and care for the plaintiff.

145. The fact that the plaintiff was not brought to the CCU postoperatively, was a common situation. It could arise due to pressure on beds in the CCU. That was why there were step down cardiac units in the hospital. She was of opinion that it was appropriate in the circumstances for the plaintiff to be sent to the Robert Adams Ward.

146. Ms. McCarthy stated that in her opinion the plaintiff had been given the appropriate standard of care; she had been assessed in respect of falls risk on admission and again after the procedure; she had been put on telemetry and a care plan had been put in place. She was closely monitored. Even with these precautions in place, it was not possible to completely eliminate all risks. All they could do was to try to minimise the level of risk.

147. In relation to the suggestion by Ms. Mudd that the plaintiff should have been put in a wheelchair and brought from her bed to the toilet by that means, Ms. McCarthy did not think that that was necessary for the plaintiff, as she was a young woman and was not physically, or cognitively impaired. There was no reason why she could not go unaided to the toilet. She did not think that it would be appropriate for a nurse to go into the toilet with the plaintiff. They would normally afford a patient privacy while in the toilet. Even in CCU, patients would be allowed to go into the toilet unaided. The fact that she had an en suite toilet in her room was good, as it meant that the nurses would know where she was at all times.

148. In relation to the suggestion that a chair should have been put in front of the plaintiff while sitting on the toilet, she had never come across such a procedure being adopted. She thought that to do so would only increase the risk of injury if the plaintiff fell.

149. Ms. McCarthy stated that even if there had been a nurse accompanying the plaintiff, the nurse would not try to catch her if she fell, as this would pose a risk of injury to the nurse herself. Thus, even with 24 hour supervision, it was possible for patients to fall and be injured. One cannot absolutely prevent people falling. You try to minimise the risk of falling.

150. In cross examination, Ms. McCarthy accepted that the nurses must draw up a care plan so as to minimise the risk of falling. It is necessary to do specific things for the patient, such as assess the risk of falls. She accepted that even with a zero score on Stratify, one must still do a risk assessment in respect of the particular patient and the risk of falling. She accepted that one would have to look at all risks which might cause falling, not just at mobility issues. However, there were no grounds for concern disclosed when the plaintiff had been assessed on Stratify on 15th May, 2014.

151. In relation to the Stratify assessment carried out on 18th May, 2014, Ms. McCarthy accepted that there had been a change in circumstances since the previous assessment and that a fall's risk had now come into play, because the plaintiff's pacemaker had been removed. She was asked where that scenario was recorded in the plaintiff's records. Ms. McCarthy stated that the risk of syncope was catered for by the use of telemetry to monitor her heart rate.

152. The witness was pressed as to where in the notes there was any reference to the plaintiff being a falls risk once her pacemaker had been removed. She stated that it made sense that if the plaintiff had abnormal rhythm and was at risk of syncope, that was dealt with by introducing telemetry and that it was necessary for the nurses to know where the plaintiff was at all times. The care plan provided for telemetry. It was specific to the particular issue which was causing the plaintiff to be at risk of falling. The telemetry care plan was there to address her specific issue of bradycardia and syncope and that had been implemented in her care plan.

153. Ms. McCarthy stated that following the repeat falls risk assessment, which had been carried out on 18th May, 2014, the plaintiff had been found not to be at risk of falls, so no specific falls risk care plan had been implemented. She was not a falls risk according to Stratify, however, the nurses knew that AV block causes dizziness and syncope and that the plaintiff was at risk of falling once her permanent pacemaker had been removed.

154. It was put to the witness that there was no reference in any of the care plans to the plaintiff being at risk of falls. Ms. McCarthy stated that the nurses reviewed the patient's history and was aware that the permanent pacemaker had been removed and that the plaintiff was on telemetry. That would allow them to formulate an appropriate care plan. They would have seen that the hospital falls risk assessment was zero, so the plaintiff did not need the usual falls risk care plan.

155. Ms. McCarthy accepted that a patient should be informed of any specific risk that arises. Normally, the nurses would go through the care plan with the patient and also when putting telemetry on her and had informed her about the provision of a call bell. It was put to the witness that no such exercise had been carried out, even though it was possible to have a falls care plan, if there was a risk of falling. Ms. McCarthy stated that the nurses had implemented a care plan to address the plaintiff's specific risks based on what was known to them.

156. The witness stated that if the plaintiff had a fall going to the toilet, she was on a cardiac ward and in a room closest to the nurses' station, with an en suite bathroom, so she was always close to the nurses' station. It was put to the witness that the plaintiff had been allowed to ambulate freely around the ward. She stated that the idea of putting the plaintiff on ambulatory cardiac monitoring, was designed to allow her some independent mobilisation. She was asked whether that was appropriate where the plaintiff was at risk of falling. Ms. McCarthy stated that everyone had a risk of falling, but they were able to mobilise freely, unless they had specific mobility difficulties.

157. It was put to the witness that a proper care plan in the circumstances of this case, would have included a direction that the plaintiff should be confined to bed. Ms. McCarthy stated that she could not think of a situation where a person, who was not physically restricted, would be confined to bed. Even if she had been, she could have had a syncope episode while in bed. It would not be normal to confine a patient to bed where there was no physical disability.

158. It was put to the witness that if a person had a history of falls, they would need an evaluation whether that was likely to arise once the pacemaker was removed and that should have been specifically addressed in the notes, rather than being left to the nurses' discretion, so that the nurses could look at a falls risk care plan when coming on duty. Ms. McCarthy stated that the nurses had adequate information. They knew that the plaintiff was not pacemaker dependent; they knew that the doctors had made a decision to remove the permanent pacemaker without insertion of a temporary wire and to deal with that scenario, the plaintiff had been put on telemetry. In addition, the plaintiff had had normal sinus rhythm in the 36 hours prior to her fall. There was nothing to suggest any change in that condition. She felt that the nurses had managed the plaintiff well, with what they had available to them.

159. Ms. McCarthy accepted that she had not spoken to any of the nurses who had actually managed the plaintiff during her stay in St. James's Hospital. It was put to the witness that in circumstances where there was no identification of a specific falls risk in the plaintiff's records, no implementation of a plan to deal with that risk, and she had not spoken to any of the nurses who had actually cared for the plaintiff, all she could do was speculate that because the plaintiff had been on a cardiac unit, the nurses would have

known that there was AV block and a risk of falls. Ms. McCarthy stated that once the telemetry care plan had been put in place, that would be known to all the nurses who came on duty during the plaintiff's stay in the hospital. It indicated to them that the plaintiff needed heart monitoring. It was put to the witness that the existence of the telemetry care plan did not refer to the plaintiff having had previous falls, which had necessitated the original insertion of the pacemaker. Ms. McCarthy stated that she did not know what had been told to the plaintiff herself. It was put to her that there was no record of any instructions being given to the plaintiff about going to the toilet, or of the risk of micturition syncope. Ms. McCarthy stated that there was a psychological care plan in the records. As part of that, the nursing staff would have ascertained to what level of detail the plaintiff wished to be informed about her illness and her care. They would discuss her stay in hospital and what was being done. It all depended on what the patient wanted to know. She was able to ask questions if she wished to have more information. She had had a pacemaker since 2003, so she knew about her condition and had been given an opportunity to ask questions.

160. It was put to the witness that the plaintiff should have had advice and assistance when leaving her bed, particularly in light of her previous history and in light of the fact that there was no temporary wire in place. She should have been specifically advised of the risk of falling. Ms. McCarthy stated that that presumed that everyone who was a falls risk must ask permission when they wanted to leave their bed. That was not general practice. The plaintiff had been allowed to go to the bathroom. The fact that she had done so, was usual practice, even when a person had a falls risk.

161. It was put to the witness that if the patient, who was a falls risk, wanted to go to the toilet, it should be done in the company of a nurse and in general they should be confined to bed, as had been done in Sligo General Hospital in 2003. Ms. McCarthy stated that in Sligo Hospital in 2003, they probably did not have access to ambulatory telemetry at that time. Furthermore, if she did not have normal sinus rhythm when she was in Sligo Hospital, perhaps that was the reason for a different management regime. In May 2014, the plaintiff had ambulatory telemetry and had normal sinus rhythm, so it was reasonable to allow her to go to the toilet unaided. It was not the same position as she had been in when in Sligo in 2003. She thought that one was not comparing like with like.

162. Finally, it was put to the witness that if the doctors and nurses did nothing, the risk of falling could manifest itself. Ms. McCarthy stated that even if the plaintiff had been accompanied, the nurse would probably not have been in the bathroom with the plaintiff, so her presence would not have prevented the fall. The nurse would normally wait outside the toilet unit.

163. In re-examination, the witness was asked whether the plaintiff needed a specific falls' risk care plan. She stated that none was needed, as it would not have changed the care that was actually given to her.

### **The Law**

164. The principles of law applicable in this case have been long established. They were set down by Finlay C.J. in *Dunne (An Infant) v. National Maternity Hospital & Jackson* [1989] I.R. 91. While those principles are very well known, it is no harm to repeat them, lest their import be dulled by familiarity. The principles set down by Finlay C.J. were as follows:-

*"1. The true test for establishing negligence in diagnosis or treatment on the part of a medical practitioner is whether he has been proved to be guilty of such failure as no medical practitioner of equal specialist or general status and skill would be guilty of if acting with ordinary care.*

*2. If the allegation of negligence against a medical practitioner is based on proof that he deviated from a general and approved practice, that will not establish negligence unless it is also proved that the course he did take was one which no medical practitioner of like specialisation and skill would have followed had he been taking the ordinary care required from a person of his qualifications.*

*3. If a medical practitioner charged with negligence defends his conduct by establishing that he followed a practice which was general, and which was approved of by his colleagues of similar specialisation and skill, he cannot escape liability if in reply the plaintiff establishes that such practice has inherent defects which ought to be obvious to any person giving the matter due consideration.*

*4. An honest difference of opinion between doctors as to which is the better of two ways of treating a patient does not provide any ground for leaving a question to the jury as to whether a person who has followed one course rather than the other has been negligent.*

*5. It is not for a jury (or for a judge) to decide which of two alternative courses of treatment is in their (or his) opinion preferable, but their (or his) function is merely to decide whether the course of treatment followed, on the evidence, complied with careful conduct of a medical practitioner of like specialisation and skill to that professed by the defendant.*

*6. If there is an issue of fact, the determination of which is necessary for the decision as to whether a particular medical practice is or is not general and approved within the meaning of these principles, that issue must in a trial held with a jury be left to the determination of the jury."*

165. It seems to me that principles 1, 4 and 5 are the relevant principles for consideration in this case.

### **Conclusions on the Temporary Wire Issue**

166. All of the expert witnesses were agreed that Dr. Daly and Mr. Tolan had to carry out a balancing exercise when considering whether it was appropriate to insert a temporary wire in this case. They had to balance the risk of infection, which could be caused by insertion of a temporary wire, as against the risk of the plaintiff having syncope episodes and falls, if she was left without a temporary pacemaker.

167. Before considering the evidence in relation to the decision that was ultimately reached, it is necessary for the court to determine an issue of fact; whether Dr. Daly communicated with Mr. Tolan in relation to the question of whether or not a temporary wire would be inserted in this case. I accept the evidence given by Dr. Daly, Mr. Tolan and Dr. Quigley, that when Dr. Daly wrote in her letter to Mr. Tolan dated 5th March, 2014, that the plaintiff was not pacing dependent, she was effectively telling Mr. Tolan that in her opinion as the treating cardiologist, she had made the decision that no temporary wire would be necessary upon extraction of the permanent pacemaker.

168. I accept the evidence given by Dr. Daly that she had a recollection of receiving a call from the cardiothoracic team on 16th May, 2014, as they wanted to know whether it would necessary to insert a temporary wire for the plaintiff on the following day. She stated that she had instructed them that a wire would not be necessary. I accept the evidence given by Mr. Tolan that while he did not

speak to Dr. Daly personally on 16th May, 2014, one of his team had done so. This was reflected in his notes for that date. It was recorded therein that the case had been discussed with Dr. Daly. It was noted that there was increased impedance in the leads leading to the pacemaker. The patient was noted to have underlying rhythm. I further accept his explanation for his notes that the entry which read "*patient had underlying rhythm*", meant that she did not need a temporary wire. His note that read "*awaiting pacemaker check*", which was also marked with an asterisk, was specifically related to the need for a temporary wire. It was a check to see if such a wire was needed. The subsequent note read "*all ok*" and "*bloods ok*".

169. Having regard to this evidence from Dr. Daly and Mr. Tolan, which I accept, I am satisfied that, while there may not have been direct verbal communication between Dr. Daly and Mr. Tolan, there was communication between Dr. Daly and a member of Mr. Tolan's team. I am satisfied that the issue of a temporary wire was discussed and a decision was reached by the cardiologist that a temporary wire would not be required and that this decision was communicated to the surgical team. I am further satisfied that Mr. Tolan was in agreement with that decision.

170. Turning then to the issue of whether the decision not to insert a temporary wire was an appropriate decision to have made in all the circumstances, the evidence on behalf of the plaintiff, as given by Dr. Cripps and Ms. Mudd, was to the effect that, having regard to the plaintiff's prior history of falls and injury, when she did not have a pacemaker in 2003, and having regard to the low risk of infection caused by insertion of a temporary wire, the appropriate decision to have made in the circumstances would have been to have inserted a temporary wire.

171. On the other hand, the defendant's expert, Dr. Quigley, was of the view that Dr. Daly and Mr. Tolan had made the correct decision not to implant a temporary wire. This was based primarily on what was perceived as the serious risk of infection that could be caused by insertion of the temporary wire. In addition, as the plaintiff was going to be managed post operatively in a specialist cardiac ward and would be on ambulating telemetry, his opinion was that the correct decision had been made not to insert a temporary wire.

172. The court does not have to decide whether Dr. Cripps and Ms. Mudd, on the one hand, or Dr. Quigley and the treating doctors on the other hand, are correct in their respective opinions. Principles 4 and 5 of the *Dunne* case are relevant here. It is worth repeating them:-

*"4. An honest difference of opinion between doctors as to which is the better of two ways of treating a patient does not provide any ground for leaving a question to the jury as to whether a person who has followed one course rather than the other has been negligent.*

*5. It is not for a jury (or for a judge) to decide which of two alternative courses of treatment is in their (or his) opinion preferable, but their (or his) function is merely to decide whether the course of treatment followed, on the evidence, complied with careful conduct of a medical practitioner of like specialisation and skill to that professed by the defendant."*

173. I am satisfied having regard to the evidence of Dr. Quigley, that the use of temporary wires in general has declined considerably in recent years due to the recognised risk of infection that they pose. I accept his evidence that in the area of angioplasty, while he had initially inserted temporary wires in all cases, that practice had changed over the years, such that temporary wires are hardly ever used now in angioplasty operations. Dr. Quigley went on to state that in other areas of cardiac surgery, such as when a pacemaker was being replaced, due to the risk of infection caused by the insertion of a temporary wire, their use had become less common.

174. The literature referred to by Dr. Quigley supports his propositions in this regard. In particular, the Klug paper was particularly relevant. It had looked at a total of 6,319 patients. That study found an overall infection rate of 0.56% for *de novo* implantations and 0.99% for non-*de novo* implantations. The study clearly showed that the insertion of a temporary wire increased the risk of infection by 2.46 times. Indeed, in the case of a non-*de novo* implantation, the risk of infection could be higher. Thus, if the decision had been made to insert a temporary wire in the plaintiff's case, that would have given her a 2.5% chance of developing an infected pacemaker within a year.

175. Support for Dr. Quigley's statement was also found in the 2017 Heart Rhythm Society Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction, which recommended minimising the use of temporary pacing. Dr. Cripps felt that it was inappropriate for the court to have regard to that consensus statement, as it had been issued some years after the events that are the subject matter of these proceedings. If this were a case where one was seeking to criticise the conduct of a doctor on the basis of standards or literature that only became available after the date of his or her actions, then Dr. Cripps' objection would be well founded. However, where one is dealing with the converse, I am satisfied that the court is entitled to have regard to the fact that the actions which were taken by the doctor at some earlier date, were the same actions which were subsequently recommended in a consensus statement on good practice issued by a reputable medical organisation. I also accept Dr. Quigley's evidence on this aspect, which was to the effect that, while the consensus statement only issued in 2017, the data on which it was based and the general practices which it recommended, had been in existence for quite some time prior to publication of the consensus statement. Accordingly, I accept his evidence that the decision made by Dr. Daly and Mr. Tolan was in accordance with standards which were subsequently embodied in the consensus statement issued in 2017. However, one must bear in mind that the consensus statement did not state that temporary wires should never be used, but that clinicians should try to minimise their use due to the risk of infection.

176. In considering this aspect, I have also had regard to the evidence of Dr. Quigley and Mr. Tolan that the consequences of infection can be very serious. They can range in severity from the site for the pacemaker becoming infected, thereby needing treatment with antibiotics and the possible relocation of the new pacemaker to the abdomen, which would be uncomfortable for the patient; to more serious consequences, including infection of the heart, giving rise to lifelong complications. There is also some risk, albeit a slight one, of perforation of the vein, or of the heart by the temporary wire, which in the latter case can cause tamponade, which can be fatal. Indeed, it was noteworthy that Dr. Daly herself had had an experience when working in the UK, where one of her elderly patients had died due to complications arising as a result of infection caused by insertion of a temporary wire. Thus, Dr. Daly was correct to consider not only the percentage risk of infection, but also the severity of the consequences should it come to pass.

177. I also accept the evidence of Dr. Quigley and Mr. Tolan that in making the decision, it was reasonable for Dr. Daly to have had regard to the level of pacing at 2%. I accept Mr. Tolan's evidence that he would definitely put in a temporary wire where pacing was at 50%, but he would not usually do so where pacing was at 2%. He stated that somewhere in the region of 10% pacing was usually the threshold which would determine whether or not a temporary wire would be inserted. I also accept his evidence that in the weekend after he gave evidence, he was due to do four lead extraction operations, in respect of only one of which was a temporary

wire due to be inserted. I further accept the evidence of Dr. Quigley, Dr. Daly and Mr. Tolan, that in general temporary wires would be inserted in approximately 50% of cases in Irish hospitals.

178. Insofar as Ms. Mudd gave evidence that a temporary wire would always be inserted in her hospital in the UK, I prefer the evidence of Mr. Tolan that in his experience working in hospitals in Cambridge for four years and in Southampton for six years, it was not universal practice to insert temporary wires. I accept his evidence that the general practice in Ireland reflects that generally applicable in hospitals in England.

179. It was also appropriate for Dr. Daly to have had regard to the frequency of the plaintiff's syncope episodes. I accept that because she was 2% pacing dependent, that did not mean that she was having heart block for the entirety of that period. It merely meant that her heart rate fell below 60bpm, so that the pacemaker kicked in for 2% of the time. However, on the Holter report from 2003, it did show that there were heart stoppages during the 24 hour period. In considering whether a temporary wire should be used, Dr. Daly was also entitled to have regard to the fact that the frequency of the plaintiff's syncope episodes leading to falls was not high. The plaintiff had had two falls in the six months prior to February 2003.

180. It is also significant that, notwithstanding the fall which the plaintiff suffered on 18th May, 2014, Dr. Daly, Mr. Tolan and Dr. Quigley remained of the opinion that the correct decision had been made not to insert a temporary wire upon removal of the plaintiff's permanent pacemaker.

181. Taking all of these matters into consideration, I have come to the following conclusion: essentially, Dr. Daly and Mr. Tolan were faced with a choice. They had to choose one of two risks. Having regard to the fact that the risk of a fall or injury could be minimised, if not entirely eliminated in a hospital setting, if a proper care plan was put in place for the plaintiff, I find that in choosing not to insert a temporary wire on this occasion, Dr. Daly and Mr. Tolan were not negligent in their care of the plaintiff. That decision was justifiable on the grounds of the increased risk of infection that would be posed by insertion of a temporary wire, together with the severity of the consequences that could arise through infection.

182. I am satisfied on the evidence that the course of treatment followed by Dr. Daly and Mr. Tolan, complied with the careful conduct of a medical practitioner of like specialisation and skill to that professed by Dr. Daly and Mr. Tolan. While there may well be two schools of thought as to which was the appropriate course of treatment to adopt in the circumstances of this case, I am entirely satisfied that Dr. Daly and Mr. Tolan were not negligent in electing not to insert a temporary wire on this occasion.

### **Conclusions on the Management Issue**

183. In looking at this issue, it is necessary to begin by making findings on issues of fact. Firstly, I am satisfied that the plaintiff was not instructed to stay in bed after extraction of her permanent pacemaker on 17th May, 2014. She was allowed to ambulate freely around her room and around Robert Adams Ward generally. I find that the only instruction that she was given, was that she was not to go out of range of the telemetry monitor. I accept the plaintiff's evidence that she moved about her room and around the ward freely on 17th and 18th May, 2014.

184. I accept the evidence of the plaintiff and that of her husband, that she saw off her daughters from the top of the stairs on the evening of 17th May and did likewise when her husband and daughters were leaving on 18th May, 2014, at 22:00hrs. At no stage did any of the nursing staff reprimand her for being out of bed. Accordingly, I find as a fact that the plaintiff was not instructed to remain in bed after removal of her permanent pacemaker.

185. In relation to the call bell in her room, I am satisfied that the plaintiff was shown where the bell was in her room and was told that she could use it if she required assistance. However, I am satisfied that she was not instructed to use the bell if she wished to leave her bed, or go to the toilet. The defendant did not make the case that such an instruction was ever given to the plaintiff.

186. In relation to the issue whether the plaintiff suffered a loss of consciousness as a result of her fall in the toilet on 18th May, 2014, I note that there is some confusion in the hospital records. In the CCU notes, it was recorded that the plaintiff was found *"unconscious on floor, had hit head against sink"*. Whereas in the note written by the nurse who found the plaintiff after her fall, it was recorded as follows *"On checking Connie was found on toilet floor. Appeared to have bleeding from the forehead. She was conscious. Brought her back to the bed"*.

187. Having regard to the plaintiff's evidence, which I accept, that she did not know what had happened, this suggests a sudden collapse without warning, with a probable transient loss of consciousness. I find as a fact that the plaintiff had a syncope episode while in the toilet and collapsed striking her head, leading to a transient loss of consciousness.

188. Turning to the kernel of this issue, as already noted, the doctors had had to elect between two risks. They had chosen to run the risk that the plaintiff would have syncope because there was no pacemaker in situ. It was accepted by Dr. Daly and Dr. Quigley that once the plaintiff's pacemaker was removed, she would revert to her pre-morbid condition in 2003. It was known that she had had a history of falls and injury, when not on pacing in the six months prior to February 2003. All the doctors accepted that after removal of the pacemaker on 17th May, 2014, the plaintiff would once again be at risk of syncope and falls.

189. Once Dr. Daly had, for good reason, elected to run that risk, it was incumbent on her to minimise the consequence of that risk, namely that the plaintiff would have a fall and injure herself. To that end, Dr. Daly stated that she had directed that the plaintiff should be taken post operatively to CCU and should be placed on telemetry. In the events which transpired, the plaintiff was, in fact, taken to Robert Adams Ward. While Dr. Cripps and Ms. Mudd were critical of that decision, I am not satisfied that there was any negligence on the part of the doctors or hospital staff, in bringing the plaintiff to Robert Adams Ward.

190. St. James's Hospital is a busy emergency hospital in a capital city. Beds in the CCU can be taken up at short notice when emergencies arise. I accept the evidence of Dr. Quigley and Ms. McCarthy that the nursing staff in Robert Adams Ward were very experienced cardiac nurses, who were highly trained in cardiac care. It is a specialised cardiac step down ward. In addition, the plaintiff was on ambulating telemetry. She was given her own room, which was nearest to the nurses' station, which was circa 5m away. Dr. Nicola Ryan, a member of Dr. Daly's team, had directed that the plaintiff be admitted to Robert Adams Ward, when no bed was available in the CCU. In these circumstances, I do not find that it was negligent to admit the plaintiff to the Robert Adams Ward.

191. In relation to the fact that the plaintiff was on telemetry, I accept the evidence of Dr. Cripps and Ms. Mudd, that this does not prevent syncope. It merely monitored the plaintiff's heart rate in real time. It enabled the nurses to get to the plaintiff quickly if there should be a drop in her heart rate. Although, how effective the system was in reality is open to question, having regard to the discrepancies in the timings recorded in the notes in relation to her syncope episode, as referred to earlier.

192. Given that the key objective was to keep the plaintiff safe in the period when she was without a pacemaker, I find that it was negligent of Dr. Daly, either herself or through a member of her team, not to have given a clear instruction in the plaintiff's notes that she was to be confined to bed and only allowed to ambulate under supervision.

193. I accept the evidence of Ms. Mudd that this instruction should have been given to the nursing staff in writing. It should have been recorded in the plaintiff's notes. It would have been a simple matter to have given a direction such as: "*Falls risk. Confine to bed. Ambulate under supervision*", or words to that effect.

194. Dr. Daly knew of the plaintiff's prior history of syncope leading to falls and injuries. She did not inform the nurses of that. She accepted that the nurses would not have known of that history, unless they were told it. While the nurses were aware that the plaintiff's permanent pacemaker had been removed and that no temporary wire had been inserted and that she was on telemetry, they were not aware of her previous falls history. It was in the light of this lack of information, that Ms. Mudd said that she did not criticise the general care given by the nursing staff to the plaintiff. However, her opinion was that there should have been a clear instruction that the plaintiff should be confined to bed. She was of opinion that that was the appropriate management for the plaintiff, in particular, given her history of syncope and falls in 2003 when without a pacemaker. Dr. Cripps was of the same view.

195. It was suggested by the defendant that the nurses were aware of all relevant facts, because the senior nurse had been present on the ward round with Dr. Daly. In light of the fact that there was a clear allegation that there had been a want of care in the management of the plaintiff post operatively, it was surprising that none of the nurses who had actually cared for the plaintiff during the relevant period, were called to give evidence. While in certain circumstances, it is appropriate for a court to draw inferences from the fact that a party declined to call witnesses, who might be thought to be in a position to give relevant evidence on issues that are in dispute between the parties, I do not feel that I can draw any specific inference from the fact that none of the nurses were called to give evidence in this case. To do so, would be for the court to engage in speculation, which it would be inappropriate for it to do.

196. In addition to the instruction to the nursing staff, which should have been recorded in the notes, I am satisfied on the basis of the evidence given by Dr. Cripps and Ms. Mudd, that the plaintiff should have been instructed that she was to stay in bed, as there was a risk that she could fall, as she had no pacemaker in place. She should have been further instructed that if she wished to leave the bed to go to the toilet, or to go elsewhere, she should use the call bell located in her room. In the event that she needed to go to the toilet, I accept the evidence of Ms. Mudd that she should have been supervised while doing so. I prefer the evidence of Ms. Mudd to that of Ms. McCarthy in this regard. No such instruction was given to the plaintiff.

197. I accept the evidence of Ms. Mudd that allowing the plaintiff to ambulate freely was not a safe practice. To a certain extent, Dr. Quigley was in agreement with that general assertion. He was asked what should be done if a person, for whatever reason, had refused to have a pacemaker implanted, when they had a history of syncope. He said that if a person had refused a pacemaker when at risk of syncope, they should be advised not to drive a car, they should not ascend heights or go up a ladder, and they should not swim. The point being that if they were to have a syncope episode in these situations, it could cause very serious injury.

198. In this case, the plaintiff was allowed to be at a height when she did not have a pacemaker and was therefore at risk of syncope. She saw off her visitors on two occasions from the top of the stairs. If she had had a syncope episode at that time, she could have fallen down the stairs and suffered serious injury, such as a fractured skull leading to cerebral haemorrhage, as identified by Dr. Cripps, or she could have fractured her cervical spine leading to possible paralysis. Thus, allowing the plaintiff to ambulate freely around Robert Adams Ward, was in fact highly dangerous for her. She was fortunate that when she did have the syncope episode, she was in the toilet, rather than at the top of the stairs. Had it been at the latter location, her level of injury may have been of an altogether different magnitude.

199. It is also noteworthy that in the course of cross-examination, Mr. Tolan accepted that if a person did not have a temporary wire in situ, they would usually be placed on telemetry and would be in bed and be monitored. He accepted that if she had been in bed when she had had her syncope episode, she would not have been at risk of injury.

200. In the course of the evidence, the defendant laid stress on the fact that the plaintiff had been given the Stratify assessment on two occasions during her stay in the hospital; firstly, on admission and secondly on 18th May, 2014, on both of which occasions she had received a zero score, indicating that she was not a falls risk. I accept the evidence of Ms. Mudd that the Stratify assessment tool, while being a very helpful tool in general terms in predicting whether a person is at risk of falling, in fact gave a false reassurance in this case.

This was due to the fact that the questions asked under the Stratify assessment, relate to any particular mobility difficulties that the patient may have. The plaintiff in this case had absolutely no mobility difficulties at all. Accordingly, she was assessed as having a zero risk of falls. That was misleading, because she did in fact have a risk of falls, due to her prior history of syncope and falls when she did not have a pacemaker in situ. All of the doctors agreed that once her permanent pacemaker was removed on 17th May, 2014, she reverted to her pre-2003 condition and therefore was at risk of having syncope episodes and resultant falls and possible injury. Accordingly, the fact that the Stratify assessments were carried out by the defendant, was somewhat irrelevant in this case, and were certainly not sufficient to identify the known falls risk, which all are agreed, did exist.

201. Finally, an issue of causation was raised in the evidence of Ms. McCarthy and was put to Ms. Mudd in the course of cross-examination. It was also raised in the submissions made by counsel on behalf of the defendant. It was submitted that it was well known that nurses and carers are instructed not to attempt to stop a person falling to the ground, as to do so, would expose them to a risk of injury. Thus, it was submitted that even if the plaintiff had been escorted to the toilet by a nurse on the evening in question, this would not have prevented the plaintiff's fall, given the existence of that general instruction, which would be part of manual handling training given to all nursing staff.

202. I do not think that that proposition can be taken in such broad terms. While I accept that, where a patient has actually begun to fall to the ground, or to fall down a flight of stairs, a nurse or carer would be instructed not to place themselves in danger by trying to prevent the fall. This does not mean that there is no point in nurses or carers assisting vulnerable people to ambulate. It would be absurd to suggest that if a nurse or carer was assisting a vulnerable person to ambulate, they would simply do nothing if that person should start to fall to the ground. If that were the case, having nurses or carers beside a patient, or an elderly person, would be pointless. Every day nurses, and carers of the elderly in nursing homes, accompany people who are frail, or who have mobility difficulties for one reason or another, when they are ambulating. If they see that the patient, or elderly person, is starting to wobble or looks like they are about to fall, the carer will place their hands under the patient's arms, or otherwise steady them, so as to prevent a fall occurring. To that extent, they serve a very real purpose in preventing a fall ensuing. It is noteworthy that in cross-examination, Mr. Tolan accepted the broad proposition that a nurse supervising a patient when ambulating, would step in to try to prevent them falling.



203. Accordingly, I do not accept the submission that, even if there had been a nurse walking beside or behind the plaintiff as she went into the toilet, the nurse would not have done anything to prevent the fall which actually occurred. I find that if the plaintiff had been ambulating under supervision, there was a good chance that if she had a syncope episode, the nurse would have supported the plaintiff under her arms, or elsewhere, so as to prevent a fall and injury occurring.

204. An alternative proposition was also put by the defendant. It was submitted that the nurse would not have actually accompanied the plaintiff into the toilet, but would have remained outside, so as to preserve the plaintiff's dignity. That was a purely a hypothetical proposition. It would be speculation on the part of the court to say what might have happened if a nurse had brought the plaintiff to the door of the toilet and had offered to escort her into the toilet itself. That was never put to the plaintiff. We do not know what would have happened, because the plaintiff was not given that option.

205. The defendants cannot excuse their failure to ensure that the plaintiff did not ambulate freely around the ward, thereby putting herself at risk of serious injury, by inviting the court to speculate that had a nurse been present, which was not in fact the case, the plaintiff would have declined her assistance and that the accident would have happened anyway. The court is not going to speculate on an entirely hypothetical scenario, that never arose.

206. In conclusion, I am satisfied that there was negligence in the management and care of the plaintiff after her permanent pacemaker was removed on 17th May, 2014. Dr. Daly was negligent in not ensuring that clear instructions were given to the nursing staff that the plaintiff was a falls risk having regard to her previous history and therefore that she should be confined to bed and should only ambulate under supervision. As a result of that failure, the necessary instructions were not given to the plaintiff that she should stay in bed. Instead, she was allowed to ambulate freely within the range of the telemetry monitor, thereby exposing herself to a risk of serious injury. In these circumstances, I am satisfied that the plaintiff has established negligence on the part of the defendant in respect of the post-operative care given to her in St. James's Hospital. I am further satisfied that due to that breach of duty, the plaintiff suffered injury when she had a fall at approximately 23:18 hours on 18th May, 2014.

### **Quantum**

207. In relation to her injuries, the plaintiff stated that after her fall she experienced severe pain in her head. After her discharge from hospital, she went to her GP as she was very concerned about her heart condition and she did not want to return to St. James's Hospital. Her head was extremely sore at that time. Due to continuing complaints of pain in her head, her GP referred her for x-rays of her skull. These were clear. She was very anxious and worried after her fall and was unable to sleep. She had some nightmares of being in hospital. She was given anxiolytic medication by her GP, which she took until January 2018. Her anxiety state had resolved by that time.

208. The plaintiff also experienced headaches and a feeling of numbness in her head. There was a sensation in the area of the scar when she moved her head and also when resting. She has been left with a scar, which she finds embarrassing, so she wears her hair over it. When the plaintiff remained concerned about her scar, her GP had recommended that she should see Mr. McHugh, Consultant Plastic Surgeon, in August 2014.

209. By agreement of the parties, a number of medical reports were admitted in evidence in relation to the plaintiff's injuries from the both the plaintiff's doctors and the defendant's doctors. Accordingly, it is not necessary to set out *in extenso* the medical evidence in relation to those injuries; a brief summary will suffice.

210. In her first report, the plaintiff's GP, Dr. Valerie McGowan, noted that the plaintiff had suffered severe bruising to the left periorbital region, together with a cut to the left upper forehead. No suturing was required at that time. The area of bruising had settled within approximately two months of the accident. The laceration to the forehead continued to cause pain in July 2014. The plaintiff complained of altered sensation in the area of the scar. Her headaches had resolved. Sensation was altered in the area both on movement and when at rest. As already noted, the plaintiff's GP referred her for x-rays of the skull, which were reported as normal.

211. The plaintiff was seen by Mr. Matt McHugh on 28th August, 2014, some three months post-accident. She was very concerned about the scar to her left forehead. She complained of a peculiar sensation around the scar. Mr. McHugh was of opinion that there was underlying nerve damage as a result of the accident. It was too early to give a prognosis in relation to future recovery of the scar, or the nerve damage, at that time.

212. Mr. McHugh reviewed the plaintiff on 13th July, 2017, some three years post-accident. At that time, her biggest problem was numbness in her scalp. She also had difficulty sleeping, due to the fact that when she turned her head, she got a peculiar feeling in her scalp. She required sleeping tablets. Mr. McHugh was of the opinion that the underlying nerves had not recovered. He did not think that they would improve in the future.

213. The scar was still noticeable and visible. It had improved since his previous review, however, it was still whitish in appearance. It was half an inch in length. The plaintiff wore her hair so as to cover it. He was of opinion that the scar would not improve further. Accordingly, it was permanent. Plastic surgery had nothing to offer.

214. The plaintiff was reviewed by her GP on 14th August, 2015. She noted that the laceration to the left forehead continued to cause discomfort. The plaintiff again complained of altered sensation in the area, both on movement and at rest. At that time, the plaintiff remained in a situation where she had discomfort on the site of the cut, together with altered sensation in the area. The GP had decided to leave the problem to settle, as she remained hopeful that the area might settle with more time.

215. The plaintiff was seen by Dr. Mary Maguire, Consultant Psychiatrist, on 23rd September, 2014, four months post-accident. She stated that the plaintiff had become anxious since the accident and worried about the tingling feeling in her head. She found that very worrying. The plaintiff had lost faith in St. James's Hospital. She had been prescribed anxiolytic medication by her GP. Her sleep pattern was also disturbed. Dr. Maguire was of opinion that the plaintiff had experienced a traumatic event, following which she had developed arousal symptoms of sleep disturbance, which was a symptom of acute stress disorder. She had good insight into her problem and it was to be expected that her sleep disturbance and excessive worrying would abate over the following six months.

216. The plaintiff was reviewed by Dr. Maguire on 8th June, 2018, four years post-accident. She noted that her anxiolytic medication had been changed to Pregabalin, 50mg daily, which she had taken up to January 2018. She noted that the plaintiff had developed sleep disturbance and anxiety as symptoms of acute stress disorder following the accident. She had made good progress since then and her symptoms of anxiety had abated and normal sleep pattern had been restored. Psychotropic medication was no longer necessary. She was coping well without medication. The prognosis regarding her mental health was good.

217. On behalf of the defendant, a report was submitted from Thomas J. O'Reilly, Consultant Plastic Surgeon. He saw the plaintiff on 18th July, 2017, three years and two months post-accident. The plaintiff stated that she was aware of an irregular scar in her left forehead. She complained of "*tightening*" around the scar. She stated that the scar was quite sensitive to superficial contact. Turning her head to the left, bending down and closing her eyes, all caused intermittent pain and discomfort in the scar.

218. Examination revealed an oblique pale flat scar in the left upper forehead, measuring 12mm in length and 4mm in width. It was non-tender, but superficial and deep palpation elicited pain and discomfort around the scar.

219. Mr. O'Reilly was of opinion that the plaintiff had a permanent residual oblique scar on her left forehead. The appearance of the scar was satisfactory. It approximated to the transverse crease lines in her forehead. The scar was mobile and was not adherent to the underlying frontalis muscle. Deep palpation elicited pain and discomfort because there had been a crush type injury. These symptoms would be permanent. Due to the plaintiff's ruddy complexion, the pale white scar stood out more. The scar was visible on close inspection from lateral or left lateral view of the forehead. It was not visible from the front. He concluded by stating that he would classify the scar as a minor permanent cosmetic disfigurement, with permanent associated sensitivity as described. He did not recommend surgical revision of the scar.

220. Finally, the plaintiff was seen by Dr. Paul O'Connell, Consultant Forensic Psychiatrist, on behalf of the defendant. He saw her on one occasion on 3rd May, 2018. He noted that as a result of the accident, the plaintiff had experienced a period of heightened anxiety, that lasted approximately eight months. She was treated with medication for that until January 2018. She had not been on medication since then. Her mental state had remained stable. She did not report the re-emergence of any depressive or anxiety symptoms.

221. Dr. O'Connell was of the view that the plaintiff's account was consistent with experiencing an anxiety related adjustment reaction. The symptoms appeared to have largely resolved within eight months of the accident. As she had been asymptomatic at the time of his interview with her, her prognosis was excellent.

222. From the foregoing, I am satisfied that this 58 year old lady, suffered a moderate head injury as a result of her fall on 18th May, 2014. She suffered a blow to her head, which caused a laceration, which did not require suturing. However, she has been left with a permanent scar in the area of her left upper forehead. There is also permanent nerve damage in the general area, which causes her unpleasant symptoms of altered sensation in that area of her skull, both on movement and when at rest. The scar itself is permanent and will not benefit from revision surgery. In addition, the plaintiff suffered psychiatric injury in the form of anxiety and sleep disturbance, which are symptoms of acute stress disorder. This required treatment in the form of medication for approximately three and a half years after the accident. It appears that she has made a full recovery from her psychiatric injuries.

223. I have viewed the scar on two occasions. I accept the plaintiff's evidence that she is embarrassed by it and as a result, tends to wear her hair in such a way as to cover the scar. While it cannot be described as an unsightly scar, it is still a permanent scar to her face. Taking all of these matters into account, I award the plaintiff the sum of €40,000 for general damages to date. I award €20,000 for general damages into the future. To this must be added the agreed sum for special damages of €3,112.48, giving an overall award of €63,112.48.