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CARDIOLOGY RELATED COMPLAINTS

A case of dyspnoea and faintness

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Background and Chronology

Mr C was documented to have a background medical history of ulcerative colitis, an enlarged prostate and high blood pressure. He was taking regular tablets for those three conditions. He was **73** years of age when was first seen in the outpatient clinic on the **30th April 2008** by Dr T (consultant cardiologist) for symptoms of exertional breathlessness associated with faintness. His heart rate at the time was found to be slow at 49 beats per minute (*normal range: 60-100 beats per minute*) and his systolic blood pressure was found to be high at 180 mmHg (*normal range: 100-140 mmHg*). Dr T documented that Mr C's symptoms could be explained by underlying chronotropic incompetence and arranged for him to have a 24-hour heart monitor, an echocardiogram, an exercise stress test (treadmill test) and a 24-hour blood pressure profile.

Mr C was reviewed again in Dr T's clinic on the **23rd July 2008** (C. Hospital University NHS Foundation Trust – the Trust) when he then reported worsening of his symptoms. His echocardiogram was reported to have demonstrated normal pumping mechanism of the heart, and the 24-hour heart monitor was documented to have shown a single episode of atrial fibrillation occurring at 7 pm on the day of the recording. Furthermore, he was documented to have only managed 2 minutes on the treadmill before the exercise stress test had to be terminated due to symptoms of dizziness and breathlessness, with evidence on the associated ECG recording that the heart rate then had failed to rise in response to exercise, thereby constituting chronotropic incompetence (*see reference 4*). Therefore, Dr T arranged for Mr C to have a coronary angiogram to look for any underlying blockage or narrowing in any of his coronary arteries that could then be treated with either PCI[1] or CABG[2] if required. Dr T also arranged for Mr C to have a permanent pacemaker implanted in the event that the coronary angiogram had revealed no significant coronary artery disease to account for his symptoms. It was documented in the clinic letter that the procedural risks and benefits had been explained to Mr C and that he was happy to proceed with the planned arrangement.

Mr C was electively admitted for his planned coronary angiogram procedure on the **23rd September 2008**. This was performed via the right groin artery and was documented to have demonstrated a moderate 70% narrowing affecting the middle segment of one of the coronary arteries (the circumflex artery) and only mild diffuse irregularities elsewhere. It

[1] **PCI:** Percutaneous Coronary Intervention.
[2] **CABG:** Coronary Artery Bypass Grafting

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was felt that Mr C's coronary disease wouldn't require either PCI or CABG and wouldn't account for his symptoms. The team therefore proceeded onto implanting a permanent pacemaker on that same day as previously arranged. This was documented to have been performed without complications and a two-wire type pacemaker (dual chamber pacemaker) was implanted. The documented post-implantation pacing and sensing parameters of the two device pacing wires (*including the pacing threshold, P/R wave voltage size and electrical impedance*) were found to have been well within the normal range.

Mr C was documented to have undergone another exercise stress test sometime after his pacemaker was implanted, the result of which was reported by Dr T on the **23rd October 2008**. Although Mr C had managed about 4½ minutes on the treadmill this time, the test had to be terminated as he developed a fast heart rhythm, for which Dr T subsequently advised the GP to prescribe Verapamil 120 mg daily.

Mr C was reviewed in clinic by Dr S (consultant cardiologist) on the **29th April 2009**, when he then expressed his continuing troublesome exertional dizziness. A pacemaker interrogation performed on that same day revealed satisfactory pacing and sensing parameters indicating that the device was functioning normally. Dr S then arranged for Mr C to have a 7-day heart monitor and requested him to keep an accurate diary of his symptoms during those 7 days. That monitor subsequently revealed that Mr C's symptoms did coincide with an intermittent junctional rhythm. Therefore, on the **17th June 2009**, Dr S referred Mr C to Dr SH (*Consultant Cardiologist & Electrophysiologist at the Tertiary Cardiothoracic Centre*) asking for a review and an opinion. Dr S wrote to Mr C on that same day informing him of the referral.

Mr C was reviewed by Dr SH on the **13th July 2009**, when he reported to have felt better after he had stopped his Verapamil tablets beforehand. Dr SH confirmed that the abnormality on the heart monitor printouts was indeed a junctional rhythm. He agreed that cessation of Verapamil therapy was appropriate as he felt the drug might have exacerbated the symptoms. Mr C was reviewed again by Dr S, on the **9th September 2009**, when he was documented to have confirmed that his symptoms had dramatically settled after stopping Verapamil, although he continued to experience occasional dizzy spells.

Mr C was reviewed again in Dr SH's clinic on the **14th September 2009**, when it was again documented that his symptoms had much improved after discontinuation of Verapamil therapy, and that he was only experiencing occasional dizzy spells. Mr C was also documented to have been keeping active and playing badminton on a regular basis. A discussion was documented to have taken place on that day about the need for Warfarin treatment for stroke prevention but Mr C was keen to remain on Aspirin. As he was relatively asymptomatic, he was discharged from Dr SH's clinic.

On the **24th February 2010**, Mr C was reviewed by Dr S. It was again documented that he reported being active and regularly playing badminton without limitation. Therefore, no medication change was made and it was arranged for Mr C to have his future reviews in the

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pacemaker clinic rather than in the outpatient clinic.

On the **6th September 2010**, Mr C was re-referred by his GP to the cardiology department at the Trust for symptoms of breathlessness and gradual progression of his dizzy spells. He was reviewed by Dr T in clinic on the **20th October 2010**. His ECG in clinic demonstrated that the atrial pacing lead tended to pace the heart all the time while the ventricular pacing lead tended to sense the presence of intrinsic heart beats and therefore allowed the ventricle to respond by itself to the paced atrial beats, albeit with some delay (***A-pace & V-sense***). Dr T acknowledged the presence of A-pace & V-sense on the ECG and documented that he did not think it would be the cause of Mr C's symptoms. He arranged for an exercise stress test and a 24-hour heart monitor.

The exercise stress test was performed on the **18th November 2010** and confirmed a good level of physical and cardiac workload, with Mr C having managed 9 minutes on the treadmill. The exercise ECG revealed 1st degree heart block throughout the test, which was commented on by Dr T. Mr C was reported to have had no symptoms while on the treadmill and the test was terminated due to fatigue.

On the **29th March 2011**, Mr C was reviewed in the pacemaker clinic. The pacing interrogation revealed a fault with the atrial lead sensing mechanism and therefore its electrical parameters were modified by the Senior Cardiac Physiologist so as to minimise the sensing problem. Mr C was given an appointment for a further pacing check in 3 months. **However, there is no documentation contained within the PHSO[3] file of any subsequent follow up at the pacing clinic.**

On the **27th February 2012**, Mr C was reviewed by Dr T in the outpatient clinic. He and his daughter were documented to have been unhappy about the persistence of symptoms. Dr T recommended a 48-hour blood pressure monitor to clarify whether the dizziness was related to episodes of low blood pressure. He also subsequently wrote to Mr C and arranged for him to have a 5-day heart rhythm monitor.

On the **28th March 2012**, Mr C was referred for a tilt table test to look for any heart rate or blood pressure abnormality that could explain his recurrent dizziness. The test however was reported on the **9th May 2014** to have shown no abnormal findings after 40 minutes of tilting.

On the **13th June 2012**, Mr C was reviewed by Dr AH (consultant cardiologist at the Trust), who reported to have noticed on the heart monitor test some evidence of atrial pacing wire malfunction resulting in **P**acemaker **M**ediated **T**achycardia (PMT), which coincided in time with Mr C's symptoms. Therefore, Dr AH recommended that a new atrial lead be implanted and referred Mr C to Dr R (device cardiologist) for that to be undertaken. Dr AH also documented that he had explained to Mr C about the heart monitor results and about the need for a new pacing lead.

On the **20th August 2012**, Mr C had his new atrial pacing wire implanted by Dr R. Prior to the implantation procedure, it was decided with, and

[3] **PHSO:** Parliamentary & Health Service Ombudsman

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agreed by, Mr C that it would be best to also change the pacemaker generator box to a new one. The procedure was reported to have been performed successfully and without complications.

On the **18th September 2012**, Mr C was reviewed in clinic by Dr R, who then referred him to Dr SH as the most recent pacemaker interrogation revealed evidence of intermittent junctional tachycardia, while demonstrating normal pacing and sensing functions of the then newly implanted device. Dr R therefore sent the heart monitor printouts to Dr SH for advice.

On the **11th October 2012**, Mr C's heart monitor result was reviewed by Dr SH, who then wrote back to Dr R. Dr SH felt that the best way to abolish Mr C's symptoms would be to commit his heart to forced dual chamber pacing 100% of the time. Up until then, Mr C's pacemaker had been programmed in the standard way, as pacemakers should be programmed according to the guidance from the European Society of Cardiology (*page 2271 of the guidance document*)[4]. That is: to pace the heart only on demand, on the occasions when the heart fails to generate its own beats. Doing so (*i.e. pacing on demand as per the recommended guidance*) would produce optimum results in the vast majority of patients, provide maximum device battery longevity and would in addition avoid the weakening of the pumping mechanism of the left ventricle that is known to be associated with prolonged 100% right ventricular (RV) pacing in some patients (*page 2271 of the above guidance*). Dr SH documented that his experience with patients in similar situations to Mr C's strongly favoured committing them to forced dual chamber pacing which often eliminated their symptoms. Dr SH also acknowledged the potential risk of future weakening of the left ventricular function as a result of the 100% RV pacing, but felt that his intrusive symptoms would nevertheless justify the pacemaker reprogramming that he suggested.

On the **30th January 2013**, Mr C had his pacemaker device reprogrammed as recommended by Dr SH. He was subsequently reviewed by Dr AH on **13th March 2013** when he then reported almost complete abolition of his symptoms following the pacemaker reprogramming. Mr C also expressed his dissatisfaction at the length of time it took the Trust to diagnose his problem and then correct it by reprogramming his pacemaker, and requested his future care to be transferred to Dr SH. When subsequently reviewed by Dr SH on the **4th June 2013**, Mr C continued to feel well with no further dizzy spells.

Mr C complained to the PSHO as he and the Trust had failed to reach a mutually satisfactory resolution to his complaint.

Question 1:

Overall view of the cardiac care

Mr C believes not all the tests he underwent to try to resolve his problems were necessary or appropriate.

[4] **European Society of Cardiology:** Guidelines for cardiac pacing and cardiac resynchronization therapy, European Heart Journal (2007) 28, 2256–2295, http://www.escardio.org/guidelines-surveys/esc-guidelines/Documents/CP/guidelines-cardiac-pacing-ES.pdf

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I appreciate we are considering a lengthy period of care, but I would appreciate your overview as to whether the tests given were reasonable, on the basis of the symptoms Mr C described. If any tests were unnecessary, or other tests should have been considered, please explain.

Answer to Question 1:

NO.

Mr C had a permanent pacemaker implanted in view of his identified chronotropic incompetence. This is in line with the pacing guidelines of the European Society of Cardiology (*page 2261 of reference 4*). His symptoms of dizziness, which he experienced after the implantation procedure, had dramatically improved for a long while following cessation of Verapamil therapy. It was clearly documented that Mr C had virtually become symptom-free between **June-July 2009** and **July-August 2010**, living his life normally and playing badminton on a regular basis with no exercise limiting symptoms. Prior to and during that period, several interrogations of his pacemaker continued to reveal normal pacing and sensing functions of the device. It is important to note that Mr C could only manage to walk for 2 minutes on the treadmill prior to his pacemaker implantation back in **2008**, and that his exercise capacity had subsequently been shown to have considerably improved (with the aid of the pacemaker) when he managed about 9 minutes of brisk walking on the treadmill test in **November 2010**.

When Mr C's dizziness symptoms were documented (in **September 2010**) to have recurred, it was reasonable of the Trust to have conducted the several tests listed in the background and chronology section above in order to ascertain the actual underlying cause for Mr C's recurrent dizziness. The fact that those tests had shown normal findings shouldn't be interpreted as them having been unnecessarily undertaken or a waste of time. On the contrary, their negative results had helped rule out other potential causes for Mr C's recurrent dizziness. It would have been inappropriate of the Trust to reprogram Mr C's pacemaker (*to 100% forced pacing mode*) from the start and without undertaking all of the above tests, as doing so would have risked inducing long term damage to Mr C's left ventricle, and would have also risked not improving his symptoms as they could have been caused by one of the other conditions that would not - *in that scenario* - have been tested.

Question 2:

Fault with lead on the pacemaker

A new atrial lead and generator were fitted in August 2012 and Mr C believes the Trust should have identified earlier that there was a fault with the lead, which might have meant the pacemaker was not functioning correctly to regulate his heart. Please see tagged docs 5 (page 5), 7, and 8.

I would appreciate your comments as to whether the Trust's explanation about the lead is reasonable, and supported by the records.

Answer to Question 2:

When it was identified in **March 2011** that the atrial pacing wire was malfunctioning, attempts were initially made to optimise its function without having to change the lead,

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which is reasonable. When those attempts failed however and the problem persisted, Mr C's pacemaker was not changed and supplied with a new atrial lead until 17 months later, in **August 2012**. This is an unacceptably long delay which the Trust should acknowledge and apologise for; particularly given the significant symptomatic inconvenience that Mr C had endured during that period. Having said this, the impact of this failing on Mr C remains a minor one since he had suffered neither serious harm nor permanent disability as a consequence.

Question 3:

Did the Trust miss opportunities to diagnose the heart block sooner?

Mr C believes he has now been correctly diagnosed as having a heart block following the second opinion provided by The Tertiary Cardiac Centre, which said '*What I often find with these patients is committing them to dual chamber pacing is often the best way to eliminate their symptoms by shortening in the AV delay*'. The Trust followed this suggestion and Mr C's symptoms significantly diminished. Mr C believes the Trust should have explored this option sooner.

Were there any missed opportunities to diagnose a heart block (if that is the correct diagnosis) or resolve Mr C's symptoms earlier?

Answer to Question 3:

NO.

The very reason Mr C was given a permanent pacemaker was that he had chronotropic incompetence, which is a form of heart block. The term "***heart block***" relates to a number of electrical disorders in the heart. Severe forms of heart block are treated with permanent pacemakers, which is what Mr C had. The above quoted extract in the question was taken from Dr SH's statement dated **11th October 2012**, in which he expressed an opinion (based on his own experience) as to how to best manage Mr C's heart block using the existing pacemaker device. That letter did not provide a new diagnosis of heart block that wasn't known before.

In summary, Mr C's symptoms of recurrent dizziness were caused by 3 different factors that occurred in succession of each other and not simultaneously. These are:

1. ***Verapamil tablets:*** These were the cause of Mr C's dizziness in the period after the initial pacemaker implantation in **September 2008**. The symptoms stopped upon cessation of Verapamil and Mr C became symptom-free and active for almost a year afterwards (between **June-July 2009** and **July-August 2010**).

2. ***PMT***: This occurred as a result of the atrial lead becoming faulty, which was initially discovered in **March 2011** but not replaced until **August 2012**.

3. ***Junctional Tachycardia:*** This was noted on the heart monitor in **September 2012** and an opinion was provided by Dr SH in **October 2012** stating that committing Mr C's device to 100% forced pacing would be the best way to treat his

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symptoms. Therefore, Mr C's pacemaker was programmed accordingly in **January 2013**, following which Mr C's symptoms were successfully abolished.

Question 4:

If you have found any failings, please comment on how these would have affected Mr C's health.

Answer to Question 4:

The only failing identified is the 17 months' delay between diagnosing the faulty atrial lead in **March 2011** and finally replacing it in **August 2012**. As stated above, during that delay period Mr C was being inconvenienced by symptoms of recurrent dizziness (caused then by PMT). The Trust should acknowledge this and apologise for it. Having said this, the impact of the failing is a minor one since Mr C suffered no serious harm or long term disability as a consequence.

Conclusions:

- Mr C needed the pacemaker that he had implanted initially in **2008**, and it was appropriate for the Trust to have undertaken the several cardiac investigations between **2008** and **2013** to try and ascertain the underlying cause for Mr C's recurrent dizziness.

- Mr C's dizziness was intermittent and multifactorial (*caused in succession by Verapamil, PMT and junctional tachycardia*). An immediate diagnosis and a quick fix treatment were therefore understandably challenging to achieve.

The delay between diagnosing the faulty atrial lead in **March 2011** and its replacement in **August 2012** constitutes a failing on the Trust's part, the impact of which is a minor one as explained in the answer to Question 4 above.