A CASE OF ACUTE CORONARY SYNDROME

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Background and Chronology:

Mrs N (Born in June **1942**) was a reasonably fit and independent lady. Her only documented past medical history was that of hypertension, for which she was on Bendroflumethiazide and Ramipril therapy. She was **70** years of age when she attended the Accident & Emergency (A&E) department of her local hospital in the early hours of the morning of **16th January 2013** with symptoms of chest pain. The pain was documented to have initially started **4-5** days earlier affecting her back and left arm. No onset time or duration was documented. She was also documented to have experienced central chest ache the previous day (*again no time of onset was documented*) lasting for **20** minutes. The pain was documented to have radiated to the left arm and was graded **4/10** in severity, with no associated breathlessness or sweating. She was documented to have seen her General Practitioner (GP) who suspected angina. Mrs N was later woken up in the night (*no time was specified*) with further chest pain, subsequent to which she went to the Trust's A&E.

The clinical observations performed in A&E revealed normal findings (*heart rate, breathing rate, oxygen saturation, temperature and level of consciousness*) apart from a significantly high blood pressure of **196/96** mmHg. The pain score was documented as **0/10**, indicating that Mrs N was not experiencing any chest pain at the time of assessment.

The A&E clerking documentation was timed **7:15** am, but Mrs N appeared to have started having several ECG recordings undertaken in A&E well before that time. Namely, she had a total of seven ECG recordings between **3:30** and **7:30** am. The times of those ECG recordings were as follows:

03:32 am, **03:50** am, **06:49** am, **06:50** am, **07:19** am, **07:28** am & **07:29** am

There is no clinical documentation that can be timed with the ECG recordings undertaken before **7:15** am. Implicitly however, it appears that Mrs N was pain free on arrival yet her initial ECG recordings were significantly abnormal. The first ECG revealed sinus rhythm but had the following significant abnormalities:

1. T wave inversion in leads I, AVL & V2-V5
2. 1 mm ST segment depression in leads II, III & AVF
3. A deep Q wave in V2 with associated 1 mm ST segment elevation
4. 0.5 mm ST elevation in AVR and AVL.

The above abnormalities would support the diagnosis of STEMI[1] of borderline acuity, meaning that the MI appeared to have happened over six hours earlier, and could have even possibly occurred over 12 hours earlier. STEMI patients who present within 12 hours of their chest pain onset are best

[1] STEMI: ST Elevation Myocardial Infarction.

treated with Primary Percutaneous Coronary Intervention (PPCI) or thrombolysis if PPCI is unavailable.
On the other hand, STEMI patients who present later than 12 hours from their heart attack onset generally don't tend to benefit from either treatment, although in some circumstances clinical judgement could still recommend either PPCI or thrombolysis to treat specific patients of this group. The majority of STEMI late presenters are not eligible for Primary PCI or thrombolysis, and should be treated as NSTEMI[2].

Mrs N's subsequent ECG recordings were not too different from the initial ECG until **7:19** am, when her ECG then appeared to show worsening of ST elevation (*to 2 mm in lead V2*). It isn't explicitly clear from the documentation whether she was experiencing chest pain at that point, but the fact that she was given 5 mg of intravenous Morphine at **7:30** suggests that she was probably in pain then. At the same time, Mrs N was also given stat doses of Aspirin, Prasugrel and Heparin. In addition, at **7:30**, a discussion was documented to have been had with the consultant cardiologist (Dr C) who agreed that Mrs N should be transferred to the cardiac cathlab[3] (*presumably for Primary PCI*). However, Dr C also explained that he had been the overnight on call consultant for cardiology but he no longer was, and that he was simply contacted by switchboard in error. Another doctor (Dr G, designation not stated) was documented to have been contacted, and s/he was happy for Mrs N to be transferred to the cathlab. I suspect Dr G was probably the on call cardiology registrar at the time. There is no further handwritten clinical documentation detailing the sequence of events that took place on that day until **20:30** hours.

From the background history documented in the PHSO file, it seems that the consultant cardiologist starting the on call shift on that day was stuck in traffic and could not be available to perform the Primary PCI. Therefore, he instructed that Mrs N be given thrombolysis instead, which happened at **8:30** am. Unfortunately, Mrs N sustained intracerebral haemorrhage (*which is a recognised complication of thrombolysis*) at **13:30** hours and was taken to the stroke unit. A discussion was documented to have been had with the Neurosurgical Unit and it was decided that Mrs N was not suitable for operative intervention (*presumably as her operative mortality risk was too high given the so recent STEMI*). Over the subsequent days, Mrs N developed heart failure and further worsening of the brain haemorrhage. She died 5 days later, on **21st January 2013**.

Mrs N's husband was unhappy with several aspects of his wife's care and complained to the Trust. No local resolution was reached and the complaint was therefore referred to the PHSO for investigation.

Questions & Answers:

Question 1:

Was Mrs N appropriately monitored during her time in the ED? In your answer please specifically comment on the number and frequency of ECGs taken.

Answer to Question 1: NO.

[2] NSTEMI: A small or medium sized heart attack. NSTEMI patients are not treated with Primary PCI or thrombolysis. They receive initial medical stabilising treatment and coronary angiography (reference 1) two or three days later to plan their further management.

As described above, Mrs N's initial ECG of **3:32** am was grossly abnormal, yet she was not given any initial ACS[4] treatment (*Aspirin, Prasugrel and Heparin*) until some 4 hours later. This is a significant failing which the Trust should acknowledge and apologise for. While that first ECG could not provide unequivocal evidence for the need for Primary PCI, it was nevertheless abnormal enough to justify giving initial ACS treatment without delay, particularly given the fact that Mrs N had been experiencing recurrent chest pain symptoms before admission. Please see the quoted statement below from the European Society of Cardiology ((ESC) guidance[5] document on the management of STEMI emphasising on the importance of early administration of such treatment:

"**Patients undergoing primary PCI should receive a combination of DAPT with Aspirin and an adenosine diphosphate (ADP) receptor blocker** (*such as Prasugrel*)**, as early as possible before angiography, and a parenteral anticoagulant** (*such as Heparin*)" – page **2583** of reference **8**.

The frequency and times of ECG recordings are documented in page 2 above. Again, given the gross abnormality of the first ECG (and the subsequent ECGs), the A&E team should have referred Mrs N to the cardiology team earlier. Doing so could have gained valuable time and might have even resulted in her being transferred to the cardiac cathlab much sooner than **7:30** am, in which case coronary angiography and Primary PCI procedures might have been performed by the night on call cardiologist without undue delay. In that scenario, the outcome could have been much more favourable for Mrs N.

Question 2:

Mr N has raised specific concerns about the length of time between the ECG taken at 6:50 – when problems were first detected – and the next ECG at 7:20. The Trust has said this did not impact on Mrs N's care. Please comment on this.

Answer to Question 2:

Please see my answer to Question 1 above. The very first ECG of **3:32** am was grossly abnormal so the delay should be calculated from then. The fact that Mrs N might have been pain free at the time shouldn't be used as an excuse for inaction. I agree that that ECG did not fully meet the criteria for Primary PCI, but it was abnormal enough to confirm that Mrs N's recurrent chest pain was cardiac and therefore initial treatment (*Aspirin, Prasugrel and Heparin/Fondaparinux*) should have been given without undue delay, along with a referral to the cardiology team. Instead, the A&E team gave no treatment and waited for **4** hours before any action was taken. This was a failing on the part of the Trust that should be acknowledged and apologised for.

Question 3:

[4] ACS: Acute Coronary Syndrome
[5] European Society of Cardiology (ESC): ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation, European Heart Journal (2012) 33, 2569-2619, http://eurheartj.oxfordjournals.org/content/ehj/33/20/2569.full.pdf

Mrs N did not receive the recommended angioplasty because there was no cardiologist available to perform it. Mr N says this shows the on call procedures at the Trust are inadequate. Please comment on this with reference to the following:

- Should there be a handover built into the process so the night cardiologist can pass information to the day cardiologist?
- Should the night cardiologist have gone home before the day cardiologist arrived?
- Are the procedures at the Trust fit for purpose?
- If there are any flaws in the procedures what should be done to improve them?

Answer to Question 3:

This is a challenging question. This case has highlighted the gap that exists between the ideal on call system that should be aspired to, and the reality on the ground given the limiting constraints within which the NHS has to operate.

There are some inherent flaws within the consultants' on call arrangements for emergency procedures across the UK's NHS organisations, including the Primary PCI Cardiology on-call system. In an ideal world, a daily consultant to consultant handover would be expected to guard against such rare yet tragic events. However, in the vast majority of UK NHS Trusts, the on call cardiology system for Primary PCI does NOT require the on call cardiologist to be resident at the hospital at all times for the duration of his/her on call duty. Rather, the system relies on the cardiologist '*becoming available*' within **30** minutes following an emergency Primary PCI call. This means that the on call cardiologist does not have to be physically present at the hospital during the entirety of his/her on call duty, and to only become available when needed to perform a Primary PCI. Other NHS specialities (*e.g. Gastroenterology, General Surgery, Orthopaedic Surgery, Neurosurgery and vascular Surgery*) operate similar on call arrangements.

Changing the on call system to one where the consultant is resident within the hospital for the duration of his/her on call shall necessitate a major change to the current NHS consultant contract, which will be a complex and convoluted process that is likely to result in a significant expense surge to the NHS yet with no tangible additional benefit for patient care. With this in mind, it is understandable why the night and day cardiologists for many NHS organisations often do not meet for a handover process.

Having said the above, one way of testing the robustness of the Trust's Primary PCI service is to request BCIS[6] to provide us with the Trust's '*door to balloon time*'[7] data for the last two years, together with national average figures for comparison. Doing so would clarify whether the Trust's Primary PCI service needs further scrutiny; or whether it is a robust enough service and that we are dealing with an isolated unfortunate incident.

[6] BCIS: British Cardiovascular Interventional Society; The Professional Body that regulates the performance of UK PCI centres and individual operating consultants. BCIS collects and publishes PCI data on a continuing basis.

[7] Door to Balloon time: The time between attending A&E and performing angioplasty for STEMI patients. Door to balloon time data are regularly collected by BCIS for all UK PCI centres.

Question 4:

The Trust has said that what happened to Mrs N was a result of circumstances beyond their control and not a consequence of failings on their part. Is this a fair assessment of the situation or was it a failing on the part of the Trust that no on call cardiologist was available to perform an angioplasty on Mrs N?

Answer to Question 4:

There was a Trust failing as per my elaboration in the answers to Question 1 & 2 above. Namely, the significant delay encountered in A&E.

As for the unavailability of an operating cardiologist, I refer to my answer to Question 3 above. Given the complexity of the non-resident on call system, it is reasonable to accept that those were indeed circumstances beyond the Trust's control. Having said this however, it might have been helpful had the on call cardiologist had green or blue emergency lights fitted on his vehicle. However, very few UK cardiologists have such lights fitted on their vehicles so it is unrealistic to expect this particular on call cardiologist to be the odd one out. Perhaps this case could be used by the PHSO to encourage the NHS to introduce a regulation that ensures doctors who perform emergency procedures have their vehicles equipped with such emergency lighting facilities.

Question 5:

Is angioplasty the preferred treatment option for people in Mrs N's situation?

Answer to Question 5:

YES. Please see the below quoted statement from the ESC guidance document (reference 5):

"**Primary PCI—defined as an emergent percutaneous catheter intervention in the setting of STEMI, without previous fibrinolytic treatment—is the preferred reperfusion strategy in patients with STEMI, provided it can be performed expeditiously (i.e. within guideline-mandated times), by an experienced team**" – page **2581** of reference **8**.

Question 6:

What would the risks have been to Mrs N if angioplasty had been performed?

Answer to Question 6:

Primary PCI carries a 0.2% risk of significant bleeding (compared with 0.9-1.0% bleeding risk with thrombolysis). Please see the quoted ESC guidance statement below:

"**In patients with early STEMI (onset <3 hours previously) who could not undergo primary PCI within 60 minutes after first medical contact, prehospital fibrinolysis (amended to half dose in patients >75 years of age) with timely coronary angiography (6–24 hours in stable patients) and rescue PCI for failed fibrinolysis was as effective as primary PCI in reducing**

the primary endpoint, a composite of death, shock, congestive heart failure, or re-infarction up to 30 days (12.4% vs. 14.3%, respectively; RR 0.86; 95% CI 0.68–1.09; P = 0.21). However, there was a significant increase in intracranial bleeding (1.0% vs. 0.2%; P = 0.04) particularly in patients >75 years of age with fibrinolysis"[8]

Question 7:

What were the risks associated with the clot busting drugs and can the administration of the clot busting drug be linked to the intracranial bleed suffered by Mrs N?

Answer to Question 7:

The risk of intracranial bleeding following thrombolysis is **0.9-1.0%** while the risk range of serious non-cerebral bleeding is **4-13%**. Please see the below ESC quoted statement:

"**Fibrinolytic therapy is associated with a small but significant excess of strokes, with all of the excess hazard appearing on the first day after treatment. These early strokes are largely attributable to cerebral haemorrhage; later strokes are more frequently thrombotic or embolic. Advanced age, lower weight, female gender, prior cerebrovascular disease, and systolic and diastolic hypertension on admission are significant predictors of intracranial haemorrhage. In the latest trials, intracranial bleeding occurred in 0.9–1.0% of the total population studied. Major non-cerebral bleeds (bleeding complications requiring blood transfusion or that are life-threatening) occur in 4–13% of the patients treated**" – page **2586** of reference **5**.

Therefore, the administering of thrombolytic treatment can be reliably linked to the intracranial bleeding that Mrs N suffered five hours after she was thrombolysed.

Question 8:

Were angioplasty and clot busting drugs the only options available to Mrs N or could other options have been considered?

Answer to Question 8:

NO. There was a third option, which was to not administer either PCI or thrombolysis, and to only continue with conservative medical treatment (including tablets and injectable Heparins). However, doing so would NOT be expected to counteract the harmful effect of the myocardial infarction as much as Primary PCI or thrombolysis would, and the subsequent damage to Mrs N's heart would have been significantly worse. Therefore, in the circumstances, it was reasonable that Mrs N was given thrombolysis in view of the unavailability of Primary PCI. Please see the below guidance ESC statement (quote):

[8] European Society of Cardiology: 2014 ESC/EACTS Guidelines on myocardial revascularization (page 2567), European Heart Journal (2014) 35, 2541-2619, http://eurheartj.oxfordjournals.org/content/ehj/35/37/2541.full.pdf

"Fibrinolysis (*thrombolysis*) is an important reperfusion strategy, particularly in those settings where primary PCI cannot be offered to STEMI patients within the recommended timelines" – page **2586** of reference **5**.

Question 9:

Mr N believes the outcome would have been different for Mrs N if the angioplasty had been performed. What was the impact for Mrs N of receiving clot busting drugs rather than the recommended angioplasty?

Answer to Question 9:

Primary PCI has a better risk profile compared to thrombolysis, as explained in my answer to Questions 6 & 7 above. The impact of thrombolytic treatment was devastating for Mrs N, as it caused her to suffer a major intracranial bleed five hours later, which had ultimately precipitated her demise five days later. However, thrombolysis was the best available treatment at the time and its administration was justified.

Question 10:

Do you believe Mrs N's death was avoidable?

Answer to Question 10:

On the balance of probabilities, yes her death was avoidable.

If Mrs N had been started on the initial heart attack treatments from as early as **3:40** am and was subsequently referred to the cardiology team from as early as 4:00 am on **16th January 2013**, she would have been assessed by the cardiology registrar, who would have discussed her with the cardiology consultant much sooner than **7:30** am, in which case she would have – more likely than not – ended up having the primary PCI performed by the night cardiologist without undue delay. Of course, Primary PCI has its risks and therefore it can't be concluded that Mrs N's death was 100% avoidable. Rather, her death was probably avoidable, bearing in mind the risks mentioned in my answers to Questions 6 & 7.

Conclusion:

- In A&E, there was an unjustified 4-hour delay in administering initial ACS treatment (*Aspirin, Prasugrel and Heparin*) and in referring Mrs N to the cardiology team, which is a significant failing on the part of the Trust.

- The impact of the above delay is significant, as Mrs N consequently missed out on an early cardiology assessment and a timely Primary PCI that could have been performed well before **7:30** am on **16th January 2013**, which in turn might have possibly saved her life.

- The unavailability of an on call interventional cardiologist was a consequence of an unforeseen circumstance that was beyond the Trust's control. Given the nature of on call

system arrangement, it wouldn't be expected that the departing and arriving on call cardiologists would routinely meet on site for handover.

- On the balance of probabilities, Mrs N's death was an avoida
- ble one.