Scottish Parliament Region: North East Scotland

Case 201204071: Grampian NHS Board

Summary of Investigation

Category

Health: Hospitals – Orthopaedics; clinical treatment; diagnosis

Overview

The complainant (Mrs C) raised concerns about Grampian NHS Board (the Board)'s handling of her husband (Mr C)'s hip replacement operation. Equipment problems caused complications during the procedure. Following surgery, Mr C developed delirium. Although this largely resolved with time, he was required to remain in hospital for several months following his surgery.

Specific complaint and conclusion

The complaint which has been investigated is that staff at Dr Gray's Hospital (the Hospital) in Elgin failed to conduct Mr C's hip replacement operation on 31 October 2012 in a reasonable and appropriate manner *(upheld)*.

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) conduct a review of the equipment available in their theatres to ensure that their surgical teams have access to any instruments which might be required in the course of an operation; and	4 July 2014
(ii) share my findings with their surgical staff for discussion at a suitable learning forum, with particular reference to the appropriateness of decisions made during Mr C's operation.	4 July 2014

The Board have accepted the recommendations and will act on them accordingly.

Main Investigation Report

Introduction

1. Mrs C's husband (Mr C) underwent a left Exeter cemental hip replacement (hip replacement operation) at Dr Gray's Hospital in Elgin (the Hospital) on 31 October 2012. During the operation, the cement gun used to apply the joint cement broke. The surgeon removed the cement from Mr C's hip and sourced a replacement cement gun before attempting the procedure again. At the second attempt, he found that the cement began to harden more quickly than it normally would. The surgeon opted to proceed with setting the joint in place, however, this caused a fracture in Mr C's femur (thigh bone). This was repaired during the same operation.

2. Following surgery, Mr C developed delirium (severe confusion and disorientation). Although his condition improved with time, he was required to remain in hospital for several months due to poor mobility and delirium.

3. The complaint from Mrs C which I have investigated is that staff at the Hospital failed to conduct Mr C's hip replacement operation on 31 October 2012 in a reasonable and appropriate manner.

4. As the investigation progressed, my complaints reviewer identified issues concerning anaesthetic medication prescribed to Mr C whilst an in-patient in the Hospital. My complaints reviewer drew this issue to Grampian NHS Board (the Board)'s attention. Following an investigation by the Board, I decided not to comment on the matter in this report.

Investigation

5. In order to investigate this complaint, my complaints reviewer reviewed Mr C's clinical records and Mrs C's correspondence with the Board. Additional comments and evidence provided by the Board were also reviewed and advice was sought from two professional medical advisers: A consultant orthopaedic surgeon (Adviser 1); and a consultant in acute medicine for older people and general medicine (Adviser 2).

6. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. Mrs C and the Board were given an opportunity to comment on a draft of this report.

Complaint: Staff at the Hospital failed to conduct Mr C's hip replacement operation on 31 October 2012 in a reasonable and appropriate manner

7. Mr C underwent hip replacement surgery at the Hospital on 31 October 2012. The operation note recorded by the surgeon who carried out the procedure (the Surgeon) noted that Mr C's hip joint was successfully dislocated and the head of the femur removed. The femur and acetabulum (the hip socket) were then prepared for the attachment of a prosthetic (artificial) head of femur and hip socket.

8. The prosthetic head of the femur was to be secured in place by inserting a pin in the shaft of the femur which had been drilled out (the femoral canal). The pin would be held in place by bone cement. The operation note records that, upon injecting the cement into Mr C's femur, the cement gun broke. The Surgeon removed the cement that had already been injected. He noted that no 'light on a stick' or 'revision instrumentation' (tools used for re-doing a hip replacement, rather than for the initial replacement) were available. A second mix of cement was injected into the femur, however, the Surgeon found it difficult to insert the pin into the femur. It was also noted at this point that Mr C's femur was fractured. The fracture was stabilised with surgical cables and was found to have good stability. The surgery was completed with a plan to review Mr C the following day.

9. Mr C was reviewed by the Surgeon and a junior doctor (the Junior Doctor) at 10:00 on 1 November 2012. The Junior Doctor recorded that he was alert and appeared clinically well. The Surgeon explained what had happened during surgery to Mr C. Mr C reportedly understood that he would require an extended period of bed rest. Other than pain on the site of his surgery, he reportedly had no complaints and was eating and drinking well.

10. At around 21:00 on 1 November 2012, Mr C experienced a sudden onset of severe agitation. Records of a subsequent review by a doctor noted that he had become confused and agitated. A plan was put in place to provide him with intravenous fluids and to test for sepsis (an infection of the blood).

11. Mr C experienced a prolonged period of acute, then persistent, delirium. Although this largely resolved over time, at the time of writing this report, Mr C had remained in hospital as an in-patient for more than ten months due to mobility problems.

12. Mr C's family wrote to the Board on 29 December 2012 asking for information regarding Mr C's operation and what may have caused the problems that the Surgeon experienced during the procedure. The Board conducted an investigation, which included obtaining statements from the Surgeon and the anaesthetist who was present for the operation (the Anaesthetist). They also sent the broken cement gun to the manufacturer's representative for investigation in case there was a fault with the equipment which was used. My complaints reviewer was provided with copies of the evidence gathered during the Board's investigation.

13. In his written statement, the Surgeon explained that Mr C's operation had proceeded uneventfully until he injected the cement into the femoral canal. He noted that the use of a cement gun is normal practice, however, on this occasion, the gun broke. The Surgeon said that the instrument failure was successfully managed. He commented that there was no light on a stick or revision instrumentation available, as these instruments are not normally required for a primary hip replacement and elective hip revision surgery (re-doing a hip replacement) is not carried out routinely at the Hospital. The Surgeon explained that the cement which had been inserted in Mr C's femur was quickly removed from the femoral canal. He said that the femoral canal was checked and no remaining cement was found. A rasp (a tool used to prepare the femoral canal) was inserted into the canal to secure it. The femoral canal was then prepared again and, as the cement guns were stored next to the operating theatre, a replacement gun and cement were quickly found. The new gun was used to inject cement into the femoral canal and the prosthesis's pin was introduced into the canal. The Surgeon commented that, normally, the cement would begin to harden after around five minutes. However, on this occasion, it began to harden after around three minutes. This made inserting the pin into the femoral canal difficult. By the time the cement began to harden, the pin was inserted roughly half-way and was beyond the point that it could be easily removed without revision instrumentation. The Surgeon said that there were only a few seconds to decide whether to remove the pin, let the cement harden and abandon the procedure with the pin half-inserted, or try to complete the insertion.

14. The Surgeon explained that, had the pin been removed, Mr C would have required a second operation shortly after this first attempt. This may have required longer in surgery than proceeding with the work required to address the complications being experienced. As such, the Surgeon elected to proceed

with insertion of the pin into the rapidly hardening cement. The pin was inserted and the hip joint put back in place. Upon checking the new joint's stability, the Surgeon found that Mr C's femur was fractured. The Surgeon advised the Anaesthetist that the procedure would, therefore, be longer than planned. Another orthopaedic consultant was asked to assist to minimise the length of the procedure and he and the Surgeon proceeded to stabilise the fracture using orthopaedic cables. The Surgeon recommended that Mr C be monitored in the High Dependency Unit for a 24 hour period, given the complications experienced during his surgery.

15. The Anaesthetist also provided a written statement. He explained that Mr C had been given a spinal anaesthetic at 09:35 and received sedation and oxygen during the procedure. When it became apparent that there had been a problem with the cement gun, the Surgeon communicated this to the theatre team. The Anaesthetist said that he was required to make a decision whether to continue with the spinal anaesthetic, or whether to induce general anaesthesia (essentially, whether or not to keep Mr C conscious for the remainder of the procedure). The Anaesthetist concluded that the spinal anaesthetic was satisfactory but planned to convert to general anaesthesia if the spinal started to wear off or if complications ensued. He commented that he wished to avoid general anaesthesia if possible, however, this was not ultimately possible. Mr C was given a general anaesthetic at 12:40 when his spinal anaesthetic began to wear off. Mr C was under sedation for three hours prior to general anaesthesia and for a further 57 minutes under the general anaesthetic.

16. When responding to Mrs C's complaint, the Board noted that the Hospital used a cement mixing system which is widely used across the NHS in Scotland. The system uses a cement gun, a cartridge with integrated mixing paddle and a nozzle. The system is used to mix and deliver pre-measured packets of cement. Following the equipment problems during Mr C's operation, the Board sent the cement gun and insert along with the batch numbers of the cement used to the equipment's manufacturer (the Manufacturer) for analysis.

17. My complaints reviewer was provided with a copy of the Manufacturer's findings following their investigation into the cement gun's failure. They found no evidence of a possible product defect with the gun. Furthermore, a review of the production notes for the cement used during Mr C's operation concluded that the batches were prepared in accordance with the Manufacturer's quality

management system and that all of their quality control tests were passed successfully. The Manufacturer acknowledged the Board's reports that the cement had hardened more quickly than normal. They explained that a number of factors can influence the rate at which the cement may harden, including room temperature, the equipment and prosthesis used, humidity, storage conditions and mixing technique.

18. My complaints reviewer asked Adviser 1 to comment on the events which took place during Mr C's surgery. Adviser 1 commented on what he considered to be the most likely sequence of events based on the Surgeon's operation note and written statement.

19. Adviser 1 said that the primary problem in Mr C's case was the breakage of the cement gun. The exact cause of this was uncertain, however, Adviser 1 said that incorrect assembly of the gun and its cartridge would appear to have been the most likely cause. He noted that, at the time of the gun's breakage, some cement had already been inserted into Mr C's femur. The gun's breakage evidently prevented the Surgeon from being able to insert all of the cement mix. The prosthesis was not inserted and the cement was removed from the femur.

20. Adviser 1 noted that the Surgeon had recorded that he did not have a light on a stick or a revision instrument available during the procedure. Adviser 1 explained that the light on a stick would be used to aid visualisation down the femoral canal. A revision instrument is a long tool, used to remove cement from the femoral canal. Adviser 1 considered that, in the absence of these instruments, the Surgeon may not have been sure that all of the cement had been removed.

21. Adviser 1 highlighted that, when the second mix of cement was inserted down the femur with the replacement cement gun, the Surgeon had found it 'difficult' to fully insert the prosthesis. He noted the Surgeon's statement that the cement had begun to harden unexpectedly early, after only three minutes. Adviser 1 said that he found this to be unlikely. He explained that cements normally harden after ten to eleven minutes and he had never encountered hardening after three minutes, even in high ambient temperatures. Such temperatures bring the hardening time down to approximately nine minutes, but never less than this. Adviser 1 considered it far more likely that there was still cement remaining in the femur from the first insertion attempt and that this had hardened. He commented that the insertion of the prosthesis was likely

described as 'difficult', as it required considerable force to advance the prosthesis down the femur against the already hardened cement. Adviser 1 considered that the force required was likely to have led to the fracture of Mr C's femur. He felt that the Surgeon should have checked that the prosthesis would have passed easily down the femur before the second cement insertion. If the Surgeon did check, there was no record of this in his operation note. Regardless of the cause of the block to the prosthesis' insertion, Adviser 1 considered that it was unwise to continue to advance the prosthesis using excessive force, as the possibility of a fracture of the femur is well recognised by surgeons involved in hip replacement surgery.

22. When commenting on a draft version of this report, the Board highlighted that, after removing the first batch of cement from the femoral canal, the space in the femoral canal was secured with a rasp which was larger than the stem of the prosthesis that was to be fitted. They considered that this demonstrated that the Surgeon checked the femoral canal before proceeding with the second insertion and that it was clear of cement. The Board, therefore, considered this to be evidence that the second batch of cement had unexpectedly hardened, causing difficulties with the reinsertion of the prosthesis. My complaints reviewer asked Adviser 1 to comment on the Board's opinion. Whilst he acknowledged that the rasp had been used, he reiterated that it would have been good practice to test the femoral canal with the prosthesis, rather than a rasp, which comes in different sizes, before proceeding to insert the cement. He remained of the view that it was very unlikely that the cement would have hardened as quickly as was suggested by the Board. Further, whether the prosthesis' insertion was made difficult by residual cement from the first insertion, or rapidly hardening cement, Adviser 1 considered it a surgical error to proceed by forcing the prosthesis into place, fracturing Mr C's femur.

23. My complaints reviewer asked Adviser 1 whether Mr C's leg fracture had been treated appropriately. Adviser 1 said that securing the fracture with cabling was appropriate in the circumstances.

24. With regard to Mr C's post-operative delirium, my complaints reviewer asked Adviser 2 whether there could have been a link between the events that took place during surgery and Mr C's delirium. Adviser 2 confirmed that this was possible. He explained that the unanticipated extended duration of the operation could have made post-operative cognitive dysfunction (POCD) more likely to occur, but it may still have occurred had the operation been

uncomplicated and shorter. Adviser 2 commented that he had found no evidence in the records that would link the specific surgical problems Mr C encountered to POCD. Furthermore, there was no evidence to suggest that any aspect of the anaesthetic management of Mr C's surgery made POCD any more likely to occur. Specifically, the operation records do not suggest that there was any significant period of low blood oxygen (hypoxia) or blood pressure (hypotension) that might have made POCD more likely to occur.

25. My complaints reviewer asked Adviser 2 whether there was anything the Board's staff could have done to prevent, or better manage, Mr C's delirium. Adviser 2 explained that there is no evidence that pre-operative assessment of a patient's cognitive function will prevent POCD. However, such an assessment can be a useful means of evaluating a patient's risk of POCD and quantifying the extent to which they may have been affected post-operatively. That said, pre-operative cognitive assessments are not currently routine in Scotland and there would have been no obligation on the Board's part to carry out such an assessment in Mr C's case.

26. Adviser 2 considered that Mr C's delirium was investigated appropriately. Metabolic upset, pain and infection, which are common causes of delirium, were promptly investigated. The possibility of a drug withdrawal syndrome was appropriately considered and managed. A cerebral computerised tomography (CT) scan, which might detect evidence of a stroke during, or shortly after, surgery was undertaken quickly. Psychiatric and medical input was sought and obtained appropriately and promptly.

27. In his written statement following Mrs C's complaint, the Anaesthetist said that he had reviewed his own practice as a result of Mr C's experiences. He explained that he now discusses the potential for POCD with all patients having major joint surgery, both in the pre-operative assessment clinic and as the responsible anaesthetist on the day prior to surgery. He noted that he had not seen Mr C's abnormal blood test results prior to surgery. Again, he changed his practices to check all investigations personally. He also noted that the Board are considering incorporating screening checks carried out by their Alcohol Liaison Nurse into the pre-operative assessment protocol.

Conclusion

28. The evidence that I have seen leaves me in no doubt that the cement gun's breakage led to Mr C's surgery being prolonged and to his femur being

fractured. It is less clear whether the prolonged time in surgery caused or contributed to his subsequent delirium, however, it certainly would not have assisted his chances of avoiding POCD. I accept Adviser 2's comments that POCD is a recognised complication of successful major joint surgery and I am satisfied that Mr C's delirium was subsequently managed appropriately. I was also pleased to learn of the steps taken by the Anaesthetist to review his, and the Board's, working practices as a result of Mr C's experiences.

29. I found insufficient evidence to conclude that the cement gun broke as a result of incorrect preparation by the surgical team rather than a product defect. I accept that the gun breaking may have been beyond their control. However, I was concerned by some aspects of the subsequent management of the situation.

30. A replacement gun and cement mix were quickly obtained and the Surgeon appropriately sought to clean the femoral canal of any cement that had been inserted in preparation for a second attempt. I acknowledge the Surgeon's and the Board's position that the femoral canal was successfully cleared of all cement. However, I accept Adviser 1's comments and agree that the events suggest that the femoral canal was likely obstructed by some residual cement from the first cement insertion.

31. I was concerned to note that the Surgeon did not have access to revision instrumentation during the surgery, as this would have improved his ability to ensure that the femoral canal was properly prepared for the second insertion attempt. Although I acknowledge that this equipment is not kept at the Hospital due to it rarely being required, a revision instrument and light on a stick would clearly have been useful in Mr C's case.

32. I note Adviser 1's view regarding the Surgeon's decision to proceed with the operation when it became apparent that completing the prosthesis insertion would be difficult. In particular, I note his comment that fracturing the patient's femur is a recognised risk of using force to complete the insertion. I acknowledge that the Surgeon was in a difficult position with very little time to make a decision as to how to proceed. His statement indicates that he considered the options available to him and reached a decision that he considered to be in Mr C's best interests. Whilst I am satisfied that the Surgeon exercised his clinical judgement in a reasonable way, the fact remains that his decision directly led to Mr C's fracture.

33. The evidence I have seen indicates that the surgical team reacted promptly to the cement gun's failure. In terms of replacing the equipment and repairing Mr C's fracture, I found their actions to be entirely reasonable. However, the absence of certain instruments and the decision to force the prosthesis through the rapidly hardening cement led to significant complications for Mr C, which left him with protracted post-operative problems. With this in mind, I uphold this complaint.

Recommendations

34. I recommend that the Board:	*Completion date*
(i) conduct a review of the equipment available in their theatres to ensure that their surgical teams have access to any instruments which might be required in the course of an operation; and	4 July 2014
(ii) share my findings with their surgical staff for discussion at a suitable learning forum, with particular reference to the appropriateness of decisions made during Mr C's operation.	4 July 2014

35. The Board have accepted the recommendations and will act on them accordingly. The Ombudsman asks that the Board notify him when the recommendations have been implemented.

Annex 1

Explanation of abbreviations used

Mrs C	The complainant
Mr C	The complainant's husband
The Hospital	Dr Gray’s Hospital in Elgin
The Board	Grampian NHS Board
Adviser 1	A professional medical adviser to the Ombudsman
Adviser 2	A professional medical adviser to the Ombudsman
The Surgeon	The Consultant Orthopaedic Surgeon who carried out Mr C's operation
The Anaesthetist	The Anaesthetist for Mr C's operation
The Junior Doctor	A Junior Doctor for the Board
The Manufacturer	the manufacturer of the cement gun and cement mix used during Mr C's operation
POCD	Post-operative cognitive dysfunction

Annex 2

Glossary of terms

Exeter cemental hip replacement	hip replacement operation
Femur	thigh bone
Delirium	severe confusion
Acetabulum	hip socket
Femoral canal	a cavity drilled into the shaft of the femur
Revision instrumentation	tools used for re-doing a hip operation
Sepsis	an infection of the blood
Hypoxia	low blood oxygen
Hypotension	low blood pressure