**Scottish Parliament Region: Mid Scotland and Fife**

**Case 200801143: Forth Valley NHS Board**

**Summary of Investigation**

***Category***

Health: Hospital

***Overview***

The complainant (Mr C) raised concerns regarding the orthopaedic treatment he received at Stirling Royal Infirmary (the Hospital). Mr C was involved in a motor cycle accident on 11 September 2007 and he sustained a fracture of his right tibia. He underwent an operation to treat this fracture on 12 September 2007 and he expressed concern with the standard of this surgical treatment.

***Specific complaint and conclusion***

The complaint which has been investigated is that a nail inserted in Mr C's right tibia was excessively long and resulted in Mr C suffering unnecessary pain and inconvenience (*upheld*).

***Redress and recommendation***

The Ombudsman recommends that the Board apologise to Mr C for the failings identified in this report.

The Board have accepted the recommendation and will act on it accordingly.

## Main Investigation Report

### Introduction

1. Following a motor cycle accident on 11 September 2007, the complainant (Mr C) was admitted to Stirling Royal Infirmary (the Hospital). X-rays showed that he had sustained fractures to his right tibia and fibula and he was transferred to the Orthopaedic Department on 12 September 2007. He was reviewed by the on-call Consultant (the Consultant) and treatment options were discussed with Mr C. The notes indicate that Mr C agreed that intramedullary nailing of his tibia fracture was the preferred option and the Consultant carried out the surgery that same day.

2. During the operation it became apparent to the Consultant that the size of nail he had intended to use was not available and he used a different sized nail instead. This nail was subsequently shown to be protruding from the end of the bone near to Mr C's knee. Although Mr C's fracture appeared to have been satisfactorily aligned, he continued to experience pain due to the protruding nail and, consequently, the Consultant carried out further surgery on 14 November 2007. During this operation, the nail was removed and a smaller one was inserted.

3. The complaint from Mr C which I have investigated is that a nail inserted in Mr C's right tibia was excessively long and resulted in Mr C suffering unnecessary pain and inconvenience.

### Investigation

4. In writing this report I have had access to Mr C's medical records and the complaints correspondence with Forth Valley NHS Board (the Board). In addition, I obtained advice from one of the Ombudsman's advisers (the Adviser), who is a consultant orthopaedic surgeon.

5. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. An explanation of the abbreviations used in this report is contained in Annex 1 and a glossary of terms is at Annex 2. Mr C and the Board were given an opportunity to comment on a draft of this report.

**Complaint: A nail inserted in Mr C's right tibia was excessively long and resulted in Mr C suffering unnecessary pain and inconvenience**

6. In an undated letter, received by the Board on 7 March 2008, Mr C complained of poor communication within the Orthopaedic Department and he stated his belief that the treatment he received was 'negligent'. He raised his concerns over incorrect equipment being used and he expressed his dissatisfaction with the length of time it took the Hospital to 'admit to making a mistake'. He noted that it took the Hospital over two months to rectify the problem and he stated that this resulted in his losing two months of healing time. He said that this affected him financially as he had received no pay from his job and that his home was also under threat as it was tied in to his job and his contract was reviewed annually.

7. The Board wrote to Mr C on 31 March 2008 and 12 May 2008 advising that their investigation of his complaint was still ongoing and apologising for the delay. Mr C then wrote to the Board again on 16 June 2008 and in this letter he advised that his contract of employment had been terminated due to his having been unfit for his role for nine months. He stated that 'had the operation been performed correctly in the first instance I would have been back at work some considerable time ago and termination of my employment and loss of home could have been avoided'.

8. The Board responded on 8 July 2008 and advised that, midway through the operation, the Consultant had been made aware that the nail inventory did not include a nail of the specific diameter which he had intended to use and he, therefore, selected a different diameter nail. They stated that, upon inserting the nail, it became jammed in the canal with approximately three quarters of an inch protruding from the insertion point in the upper tibia and, despite repeated efforts to advance or retract the nail, it refused to move. They said that the position was accepted because the part of the nail protruding appeared to be surrounded by soft tissue and was not thought to be encroaching on the knee cap or the femur.

9. The Board advised that the Consultant had intended to leave the nail for around six weeks, as the thin layer of tissue around such implants usually loses substance, which would loosen the nail and allow it to be removed and exchanged for a new nail of a differing dimension. They noted that, when Mr C underwent exchange nailing on 14 November 2007, the nail backed out easily, as foreseen by the Consultant. They stated that the Consultant, therefore, felt

that his management of Mr C's care was entirely appropriate and he did not agree that his actions had been negligent.

10. With regards to Mr C's concerns that the standard of communication in the Orthopaedic Department was 'extremely poor', the Board advised that this had been acknowledged by staff and was being addressed within the department.

11. Prior to responding to Mr C's concerns, in email correspondence between the Board's Patient Relations Team, the Consultant and other members of staff, it was broadly recognised that Mr C's complaint might result in litigation, however, it was decided to defer any further comment on this matter to their Central Legal Office (the CLO). During the course of my investigation, I contacted the Board to enquire about what, if any, suggestions or comments the CLO had made in light of Mr C's complaint and they confirmed that the CLO had not yet had any involvement in the case because no 'claim' had been formally intimated by Mr C. Mr C subsequently advised me that he had considered taking legal action but that he could not afford to.

12. The Ombudsman received a complaint from Mr C on 10 September 2008 and, in his letter, he disagreed with the Board's assertion that he had chosen to have the nail after the Consultant had explained the various treatments available to him and had discussed the benefits and any possible complications. He stated that, due to the high dosage of pain medication he was receiving, he could only remember being told that he could have the bones held in place with a nail or that a cast could be applied. He said that the Consultant thought he would be best to choose the nail and he agreed as 'it is only natural you would trust the opinion of a healthcare professional'.

13. Mr C also noted that the Board had said the Consultant had not been aware that the nail he had intended to use was not available until he had begun to operate. Mr C believed that this should have been checked beforehand and, in finding that the nail was not available, a plaster cast should have been used instead.

14. Mr C reiterated his belief that the loss of his employment could have been avoided by either having used the correct nail in the first place or having had a plaster cast fitted instead. He also reiterated his concerns regarding the standard of communication within the Orthopaedic Department.

*Adviser's view*

15. I asked the Adviser to review the medical notes relating to Mr C's treatment. The Adviser noted that, in email correspondence between the Consultant and the Board's Patient Relations Team, the Consultant indicated that he had been assured by the theatre staff that the stock of nails was adequate. When the chosen size turned out not to be available, a larger diameter nail was used and the Consultant noted that it became jammed in the bone canal and that, despite repeated efforts to advance or retract the nail, it refused to budge. The Adviser also noted that the Consultant stated in email correspondence that 'The equipment used and the technique used were entirely appropriate for [Mr C]'s injury. It is of note that this was not the first time that I had been informed in the course of a procedure that the nail of required length and diameter had not been stocked'.

16. The Adviser then noted that, in the same email correspondence, the theatre manager responded to the Consultant's comments and stated that the desired nail 'was not available because it was not part of the normal range and, in fact, was never stocked'. She also indicated that the Consultant's second choice of nail size had also been unavailable and she stated that 'again that size is never stocked … a fact I would have believed [the Consultant] to be aware of'. She did note that the second size choice had been available within a range manufactured by another company but that it was not the Consultant's practice to use this range of equipment.

17. The Adviser checked with the company who manufactured the range of nails which the Consultant preferred to use (the Company) and they confirmed that the desired size of nail was available, however, he noted from the correspondence that the operating theatres at the Hospital did not stock this size. He advised that it would have been appropriate for the Hospital to have stocked a wider range of tibial nails in terms of diameter, although he noted that the available lengths seem to have been appropriate. He confirmed that it was the responsibility of the orthopaedic theatre manager to ensure that an appropriate inventory of nails was available at all times and, if stock was deficient, the orthopaedic surgical team should have been informed.

18. With regards to Mr C's belief that the Consultant should have been aware of the lack of availability of the desired nail in advance of the operation, the Adviser confirmed that the measurements made at the time of surgery would

establish the length and diameter of nail required and it would, therefore, not be possible for the surgeon to decide on the size of nail at an earlier stage.

19. When carrying out the surgery, the Adviser noted that it was normal practice to widen the canal inside the bone to a size sufficient to accommodate the chosen nail so that it can be inserted without difficulty. He informed me that the operative technique advised by the Company emphasised that the canal should be widened to 1 millimetre larger than the nail chosen and that the nail should only be inserted with 'gentle hammer blows'. The Adviser said that there was no requirement for the nail to be tight fitting within the canal, since nails were locked at both ends with cross screws which maintain appropriate stability between the nail and the bone. He stated that, if a nail proved difficult to advance, it was not appropriate for the surgeon to continue hammering it into the bone as it may shatter the bone or become jammed and impossible to advance further or remove. The Adviser noted that the latter scenario, ie jammed nail, was what happened in Mr C's case.

20. In addition, the Adviser stated that, in Mr C's case, the entry point for the type of nail used was inappropriate and the shape of the nail was not ideal for the pattern of Mr C's fracture. He advised that it was clear from the radiographs that the insertion point was more posterior (towards the back) than was appropriate for the nail type and he suggested this may have contributed to the difficulty the Consultant had in inserting the nail correctly. He also advised that in fractures of Mr C's type, the chosen nail could cause malalignment of the tibia and he noted that this was demonstrated in Mr C's post-operative x-rays. He stated that an alternative nail produced by a different manufacturer, with a different shape, would have been more appropriate in this case.

21. The Adviser acknowledged that the Consultant may have been familiar with the operative technique of the particular nail type chosen and that satisfactory insertion could have been achieved providing due care was taken. However, in the Adviser's view, it was not acceptable for the Consultant to have allowed the nail to become jammed within the canal of the bone such that he could neither remove it nor advance it. He noted that the Consultant made no comment about this in the operation note, which read as if the operative procedure was quite uneventful.

22. Having encountered the complication of being unable to advance or remove the nail, the Adviser said that it was appropriate for the Consultant to

have left the nail in place, as it was possible to close the skin over the wound. He stated that the matter should then have been discussed with Mr C and an exchange nailing should have been arranged for a later date, usually between three and six weeks after the first operation. He indicated that the Consultant was quite right in stating that a small amount of bone necrosis occurs around the nail which allows its later removal. However, the Adviser noted that Mr C did not appear to have been informed that there was a problem until 2 November 2007, when he attended out-patients, despite having been re-admitted to the Hospital and having a post-operative x-ray on 18 September 2007. The Adviser did note that the radiographs taken on that occasion did not demonstrate the protrusion very well due to the position of a label along with the fact that the end of the tibia was cut off in one of the pictures. Nevertheless, the Adviser was of the view that the Consultant had clearly been aware of the fact that the nail was protruding and had failed to inform Mr C of this. In addition, the Adviser observed that the Consultant had noted the nail to have been protruding by three quarters of an inch, however, he advised that the x-rays showed that the protrusion of the nail was significantly more than this.

23. When the Consultant carried out the exchange nailing, the Adviser noted that he inserted a nail with a smaller diameter but of the same length as the original nail. He indicated that, although the operation note stated that the tip of the nail was flush with the surface of the tibia, this did not appear to have been the case and the post-operative radiographs showed that the nail was still protruding from the upper end of the tibia by at least a centimetre. He advised that the Consultant's first choice of nail had, in fact, been longer than the length of nail used in both operations and, as the nail used was subsequently shown to have been too long for Mr C's tibia, his initial choice of nail would, therefore, have been too long also. The Adviser stated that, since Mr C's fracture was above the mid point of the tibia, it was not necessary to have used such a long nail. He advised that, in his view, had the Consultant used a shorter nail in the first instance, and had he widened the bone canal to a larger size, then the insertion of the nail at the first operation would probably have been uneventful.

24. The Adviser noted that, following Mr C's discharge from the Hospital after his first operation, he was re-admitted with an infection to the lower part of his leg. He advised that this was not connected to the intramedullary nailing procedure and that it was almost certainly related to the abrasion that Mr C had

on the side of his leg as a result of his accident. He stated that this was entirely appropriately managed by intravenous antibiotics, rest and elevation.

25. With regards to Mr C's concerns regarding a delayed healing time due to the problems encountered, the Adviser informed me that it is generally accepted that healing time for closed fractures of the tibia is between 16 and 20 weeks. However, he advised that transverse fractures, such as Mr C's, often take somewhat longer to heal than oblique or spiral fractures. He stated that it would not be reasonable for a patient who undertakes a heavy physical occupation to expect to return to that occupation, after a fracture such as that sustained by Mr C, for at least four or five months. In the Adviser's view, it was unlikely that the requirement for a second operation in Mr C's case would have delayed healing by a significant amount. However, he advised that it was the case that the protruding nail delayed Mr C's recovery after the first operation, in terms of mobilisation of the knee.

26. The Adviser said that the inappropriate operative technique, which resulted in the nail protruding from the tibia by 3 centimetres, had led to some abrasion to the under-surface of the kneecap which was noted at the second operation. He advised that it also prevented Mr C from flexing his knee beyond 75 degrees and resulted in him having more pain than would normally have been expected. The Adviser informed me that up to 35 percent of patients undergoing intramedullary nailing of the tibia developed persistent knee pain but that this was likely to be more significant when the nail is excessively long, as was the case with Mr C.

27. The Adviser summarised that the Consultant had made the wrong choice and that the nail he had initially wanted to use, which was not available, was far too long. In addition, he advised that the nail which was eventually used was also too long and, in his opinion, the Consultant's comment that the nail became stuck because the diameter was too large was inappropriate as he could have widened the bone canal to a larger size to accommodate the increased diameter. The Adviser also stated that the type of nail chosen was not the most appropriate for the particular pattern of fracture. He stated that a better alignment could have been obtained had a nail with a more proximal (central) bend been used and he confirmed that such nails were available in the department. He confirmed that the malalignment caused by the poor surgical technique had left Mr C with a malunion of his tibia, although he pointed out that the alignment is not significantly abnormal and, in his view, Mr C was unlikely to

suffer an adverse outcome from this. However, he indicated that this still demonstrated that inappropriate techniques were used in the treatment of Mr C's fracture.

28. The Adviser highlighted that Mr C had sustained considerable increased disability and pain as a result of the operative procedure carried out on 12 September 2007 and the situation could have been avoided, both by better surgical technique and by better assessment of the size of implant required. He said that Mr C's subsequent treatment was appropriate and that it was appropriate to revise the nail size, although, in his view, the replacement nail should have been shorter as it was still left long. Notwithstanding this, the Adviser stated that it was unlikely that Mr C's healing time or eventual outcome would have been adversely affected by the treatment he received.

29. With regards to communication, the Adviser stated that it is very important for patients to be informed of exactly what has happened when complications have occurred in order to allow a plan to be developed to rectify the situation. This had clearly not been done in Mr C's case. The original operation note made no mention of the fact that the nail was too long or that there were any difficulties during the procedure. In the Adviser's opinion, there was a significant lack of communication between the surgical team and the patient and better communication would have significantly improved the professional relationship between the Consultant and Mr C.

30. I shared the Adviser's report with Mr C and the Board on 20 May 2009 and the Board responded in a letter dated 25 June 2009. They advised that they had discussed the case with the Consultant, who no longer works for the Board, as well as the clinical lead for orthopaedics and the Associate Medical Director. They recognised that the communication between the Consultant and Mr C, as well as within the orthopaedic team was inadequate and contributed to Mr C's unsatisfactory experience. They expressed regret over this and advised me that they had taken steps recently to improve communication, both with patients themselves, and also within the wider orthopaedic team.

31. With regards to the Hospital's stock of implants, the Board referred to a Scottish Government Health Department initiative, following advice received from the Scottish Government Health Department's Chief Medical Officer, intended to lead to a migration towards single-use pre-sterilised individually wrapped orthopaedic nails in NHS Scotland by 31 December 2007. The Board

informed me that, as a result of this initiative, theatre staff had undertaken a review of nail stock and they now stocked a wider range of nails. The Board advised me that the deficiency apparent in Mr C's case was very unlikely to recur.

32. Finally, in respect of the radiographs taken on 18 September 2007 not having demonstrated the full extent of the nail in situ, the Board advised that it would have been normal procedure for the radiographer to ensure that the radiographs did include the whole length of the nail. To this end, they confirmed that they had discussed this issue within the Radiology Department and department procedures had been reviewed and staff awareness raised.

*Conclusion*

33. The advice which I have received, and fully accept, indicates that the surgical technique used in Mr C's initial operation was inappropriate and the nail used was too long. In addition, the replacement nail inserted during the revision surgery was too long. Also, the standard of communication with Mr C was poor and inappropriate, in that Mr C was not immediately informed of the problems which the Consultant encountered during the first operation. In all circumstances, I uphold this complaint.

34. I recognise that the Board have taken action to address the communication issues as well as the issues relating to stock levels of orthopaedic nails and the issue of the radiograph. Had the Board not taken these steps, I would have been making recommendations to address these issues now. In addition, I note that the Consultant no longer works for the Board. Therefore, in the circumstances of the case now, all that remains for me to recommend is that the Board write to Mr C to apologise for the failings identified in this report.

*Recommendation*

35. The Ombudsman recommends that the Board apologise to Mr C for the failings identified in this report.

36. The Board have accepted the recommendation and will act on it accordingly. The Ombudsman asks that the Board notify him when the recommendation has been implemented.

**Annex 1**

## Explanation of abbreviations used

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| Mr C | The complainant |
| The Hospital | Stirling Royal Infirmary |
| The Consultant | The orthopaedic consultant who operated on Mr C |
| The Board | Forth Valley NHS Board |
| The Adviser | The orthopaedic adviser to the Ombudsman |
| The CLO | The Central Legal Office of NHS Scotland |
| The Company | The company which manufactured the range of nails the Consultant preferred to use |

**Annex 2**

## Glossary of terms

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| Closed fracture | A broken bone that does not penetrate the skin |
| Femur | The thigh bone (extends from the pelvis to the knee) |
| Fibula | The calf bone (the outer and smaller of the two leg bones below the knee) |
| Intramedullary nailing | When a nail is inserted inside a bone to align and stabilise a fracture |
| Necrosis | The death of body tissue |
| Oblique fracture | A fracture in which the break is diagonal to the long axis of the bone |
| Spiral fracture | A fracture where the bone has been twisted apart |
| Tibia | The shin bone (the inner and larger of the two leg bones below the knee) |
| Transverse fracture | A fracture in which the break is across the bone, at a right angle to the long axis of the bone |