SPSO Scottish Public Services Ombudsman

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

SPSO
4 Melville Street
Edinburgh
EH3 7NS

Tel **0800 377 7330**
SPSO Information **www.spso.org.uk**
SPSO Complaints Standards **www.valuingcomplaints.org.uk**

Scottish Parliament Region: Highlands and Islands

Case ref: 201507970, Highland NHS Board
Sector: Health
Subject: Hospitals / Clinical treatment / Diagnosis

Summary
Mr C had a hip replacement operation at Raigmore Hospital. During the operation, he was aware that the first attempt to insert the implant into his hip had not been successful, and the surgeon had tried again. This had prolonged the time he was in theatre, and, given the length of time the operation was taking, Mr C had asked for further anaesthesia for the pain. He found the experience to be very distressing and complained that the board had not provided him with a reasonable standard of care.

I took independent advice from two advisers; one a consultant in orthopaedic surgery (adviser 1) and the other a consultant anaesthetist (adviser 2). Whilst there were some difficulties during the procedure, of which there is more detail in my full report below, adviser 1 considered that the standard of surgery was reasonable. However, adviser 2 reported that Mr C was uncomfortable for over an hour until the anaesthetist administered a general anaesthetic, and it would have been reasonable for this to have been undertaken earlier. Based on this, I upheld Mr C's complaint about the care he received in his operation.

Mr C was discharged from hospital, and he was given aspirin to take. However, around two weeks later he was readmitted to hospital with a pulmonary embolism (a clot in the blood vessel that transports blood from the heart to the lungs).

There are national guidelines, issued by the Scottish Intercollegiate Guidelines Network (SIGN) and the National Institute for Health and Care Excellence (NICE), which relate to the use of treatments to prevent VTE (the formation of blood clots in the vein). These guidelines state that aspirin is not considered an adequate treatment for reducing the risk of VTE for patients in hospitals.

The advice I received from adviser 1 is that the failure to follow the guidelines on treatment following his surgery led to a significant injustice to Mr C in that he suffered a life-threatening condition which required another admission to hospital for treatment. The surgeon who carried out the surgery had noted in

Mr C's operation note that he should receive anticoagulant therapy but another member of staff had discharged Mr C with aspirin. However, the surgeon had gone on to tell my complaints reviewer that it was common throughout Scotland for aspirin to be provided for patients who had undergone joint surgery, even though this is against recognised SIGN guidelines. The board confirmed to my complaints reviewer that there was no specific board policy on this, but that if anticoagulant therapy wasn't provided to a patient, this should be documented and explained by the clinician taking that decision.

I am very concerned not only that the relevant guidelines were not followed in Mr C's case, but also about the board's practice in general. It remains unclear to me if the board have a coherent policy that is being followed within Raigmore Hospital and beyond. As a result, an urgent review is required. I also intend to write to the Chief Medical Officer to draw their attention to my concerns about the use of aspirin and its potential implications for patient safety which have come to light in the course of my investigation.

Redress and recommendations

The Ombudsman recommends that Highland NHS Board:	*Completion date*
(i) bring adviser 2's comments in relation to anaesthesia to the attention of relevant staff;	22 July 2016
(ii) review as a matter of urgency the practice to ensure that its surgeons take into account the relevant guidelines on VTE prophylaxis;	22 August 2016
(iii) review its standard operating procedures concerning VTE prophylaxis for patients on discharge taking into account the relevant guidelines; and	22 July 2016
(iv) apologise to Mr C for the failures this investigation identified.	22 July 2016

Who we are

The Scottish Public Services Ombudsman (SPSO) investigates complaints about organisations providing public services in Scotland. We are the final stage for handling complaints about the National Health Service, councils, housing associations, prisons, the Scottish Government and its agencies and departments, the Scottish Parliamentary Corporate Body, water and sewerage providers, colleges and universities and most Scottish public authorities. We normally consider complaints only after they have been through the complaints

procedure of the organisation concerned. Our service is independent, impartial and free. We aim not only to provide justice for the individual, but also to share the learning from our work in order to improve the delivery of public services in Scotland.

The role of the SPSO is set out in the Scottish Public Services Ombudsman Act 2002, and this report is published in terms of section 15(1) of the Act. The Act says that, generally, reports of investigations should not name or identify individuals, so in the report the complainant is referred to as Mr C. The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. Mr C complained to the Ombudsman about an operation to fit a replacement hip at Raigmore Hospital (the Hospital) saying that failings led to a delay in being returned from theatre. He was discharged from the Hospital on 8 February 2014 on aspirin; however, he became ill and was readmitted to the Hospital on 27 February 2014 with a pulmonary embolism. Mr C also continued to suffer pain in the new hip joint and that, together with the effects of the pulmonary embolism, prevented him from being active or returning to part-time work.

2. The complaints from Mr C I have investigated are that Hospital staff:

(a) failed to provide Mr C with an appropriate standard of hip replacement surgery (*upheld*); and

(b) failed to provide Mr C with appropriate anti-coagulant therapy following the surgery (*upheld*).

Investigation

3. In order to investigate Mr C's complaint, my complaints reviewer examined all the information provided by Mr C. They also reviewed a copy of Mr C's clinical records and Highland NHS Board (the Board)'s complaint file. Finally, they considered the relevant guidelines and obtained independent advice from experienced consultant orthopaedic surgical and anaesthetic advisers (Medical Adviser 1 and Medical Adviser 2 respectively) on the clinical aspects of the complaint. In this case, we have decided to issue a public report on Mr C's complaint because the failings I found led to a significant personal injustice to him, and to draw attention to a practice that may be common within the Board which is contrary to the relevant guidelines and disseminate the learning from this case to other health boards.

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

Relevant guidelines

5. The Scottish Intercollegiate Guidelines Network (SIGN) publishes guidelines on the use of prophylaxis to help prevent and manage venous thromboembolism (VTE). Their publication entitled 'The prevention and management of venous thromboembolism' states that:

'the rationale for prophylaxis is based on its efficacy, the clinically silent nature of VTE, its high prevalence in hospitalised patients … and its potentially disabling or fatal consequences. There is evidence that routine prophylaxis reduces morbidity, mortality and costs in hospitalised patients at risk of deep vein thrombosis and pulmonary embolism …

Patients undergoing total hip … replacement surgery should receive pharmacological prophylaxis … combined with mechanical prophylaxis unless contraindicated …

Extended prophylaxis should be considered …

As other agents are more effective for prevention of deep-vein thrombosis [DVT], aspirin is not recommended as the sole pharmacological agent for VTE prophylaxis in orthopaedic patients.'

6. The National Institute for Health and Care Excellence (NICE) also publishes guidance on the use of prophylaxis to help prevent and manage VTE. Their publication entitled 'Venous thromboembolism: reducing the risk for patients in hospital' states that, in relation to reducing the risk of VTE, 'do not regard aspirin or other antiplatelet agents as adequate prophylaxis for VTE'.

Clinical Background

7. Mr C was admitted to the Hospital on 4 February 2014 for hip replacement surgery. A spinal epidural was administered around 14:45. The operation took longer than anticipated and a general anaesthetic was administered on 17:45. The operation concluded around 18:45. Mr C was discharged on 8 February 2014 on aspirin. However, he became ill and was readmitted to the Hospital on 27 February 2014 with a pulmonary embolism.

(a) Hospital staff failed to provide Mr C with an appropriate standard of hip replacement surgery

8. Mr C said he wanted to know what happened during the hip replacement operation as the first attempt was not successful and he spent a long time in theatre. He was conscious of the consultant surgeon (the Consultant Surgeon) violently tugging on his leg as they tried to fit the implant. He also started to feel pain given the length of time of the procedure and insisted that he be given further anaesthesia. Mr C was extremely distressed about what had happened and had disturbing flashbacks to these events.

The Board's response

9. The Board said that during the operation, Mr C's hip cup was fitted uneventfully but that the implant could not be properly fitted. Procedures were performed to try and achieve the fitting of the implant and the Board apologised if Mr C felt this to be violent tugging. The tendon muscle was cut but this did not allow a successful fit either. The Consultant Surgeon decided to remove the metal stem and fit a shorter component but this was unsuccessful as the component could not be sunk into the cement (or glue) sufficiently to allow a proper fit. The Consultant Surgeon therefore removed some of the cement, which resulted in a satisfactory fit of Mr C's joint replacement. The Consultant Surgeon was unable to say why Mr C's hip could not be reduced given that the implant size and position was the same as that of the successful trial.

10. The consultant anaesthetist (the Consultant Anaesthetist) also wrote to Mr C to explain what type of anaesthetic was provided during the hip replacement surgery. They said that Mr C received a spinal anaesthetic around 14:45 which worked well for the start of surgery around 15:25. He then received sedative medication and shortly after 16:00 an opioid analgesic and morphine when he complained of some pain in his groin. Mr C received further morphine around 17:15 and when he experienced a significant increase in pain around 17:45 he agreed to proceed with a general anaesthetic. Surgery then finished at 18:45.

11. The Consultant Anaesthetist also explained that generally a spinal anaesthetic would give good pain relief for surgery for approximately two hours although this varied between individuals. When surgery was unexpectedly prolonged, sometimes a general anaesthetic had to be given. The Consultant Anaesthetist apologised that Mr C experienced significant pain before the general anaesthetic and was sorry to hear that he had had flashbacks to these events. The Consultant Anaesthetist suggested some psychological input to help with his disturbing flashbacks and said they would write to his GP to request their help with this.

Medical advice

12. Medical Adviser 1 explained that the normal surgical procedure was to insert the replacement socket first then the head or neck replacement for the thigh bone. The head/neck sits on a stem inserted into the femoral canal (the 'honeycomb' bone in the middle of the femur). Both components are fixed with bone cement (an acrylic polymer). Once the socket is fixed and the femoral

canal prepared, a trial reduction is performed to check that everything fitted, in particular that the hip was stable and the leg lengths equal. The length of the leg can be varied by choosing from a range of components and by how far down the femur the stem of the replacement was pushed. One of the results of hip arthritis could be shortening and scarring of the tissues around the hip. It was common to release tight muscles to get the hip sitting correctly (especially if the other leg was longer). In Mr C's case, despite a successful trial reduction, the hip would not reduce when the definitive replacement was cemented into place. Medical Adviser 1 said this was uncommon but happened occasionally and did not suggest poor surgery. Medical Adviser 1 agreed that a successful trial reduction should mean a successful reduction of the definitive replacement; however, most surgeons have been faced with a situation where this was not the case. Clearly there had been some subtle change between position of the trial and the final position, but that could and did happen.

13. Medical Adviser 1 further explained that the post-operative x-rays showed a satisfactory final position of the implant and equal leg lengths. To achieve this, not only did the stem of the original implant have to be removed, but also the bone cement. Medical Adviser 1 explained that bone cement was a plastic polymer that took about ten minutes to set hard enough for the hip to be stable, but that polymerisation continued for months or years after surgery. When revising a hip that has been in for years, the cement is usually well fixed to the bone and has to be chiselled or drilled out. The cement by then is quite brittle but it is still difficult to do without perforating the shaft of the femur. Perforation of the shaft of the femur is not uncommon, even in the most skilled and experienced hands. Mr C's post-operative x-rays showed that cement had leaked out the front of the femur during the final insertion indicating that the shaft had been penetrated when the first lot of cement was removed. The cement that leaked out collected in the muscles in front of the femur where it would be both invisible to the surgeon and not expected to cause a problem.

14. Medical Adviser 1 said that given the difficulties encountered during surgery, the time taken was reasonable. Medical Adviser 1 concluded that the surgery did not go smoothly and revision was required to seat the hip replacement satisfactorily, which had consequences with regard to the anaesthesia and leakage of cement into the thigh muscles. Whilst this was very unfortunate, there was no fault identified by Medical Adviser 1.

15. My complaints reviewer asked Medical Adviser 2 if reasonable actions had been taken around anaesthetic and within a reasonable time given the operation went on for longer than expected. Medical Adviser 2 said that it was recorded that an uncomplicated insertion of a spinal anaesthetic was administered (the clinical notes indicated that Mr C was keen to avoid a general anaesthetic), which was an appropriate technique particularly as the Consultant Anaesthetist was not expecting the case to be particularly long. It was not unusual for patients to experience varying degrees of anxiety during this type of procedure and some anaesthetists used additional sedation; the clinical records showed that two milligrams of midazolam (a sedative) was given before surgery (and a further two milligrams during surgery), which was reasonable.

16. Medical Adviser 2 explained that patients could feel sensations so there was a balance as to what could be tolerated and what was interpreted as significant discomfort (and what sensations may heighten existing anxiety). The balance, therefore, was knowing what additional analgesia and sedation could be added to minimise discomfort which depended on the type of discomfort complained of and at what point it was felt. Mr C's statement suggested that he was experiencing significant pain and the Consultant Anaesthetist documented that from 16:00 he was experiencing pain in the groin. Mr C was then given five milligrams of morphine and alfentanyl, which was reasonable and described as having a 'good effect'. Medical Adviser 2 commented that this was only one hour and 15 minutes from the operation start time which was a very short time for a spinal anaesthetic to begin to wear off and suggested that the block may not have been quite as complete as expected. Mr C would then have continued to experience some discomfort until a general anaesthetic was administered about 75 minutes later. While the morphine and fentanyl would have given some relief, Mr C's interpretation was that it was inadequate. Medical Adviser 2 concluded that Mr C probably did experience more pain and was uncomfortable for over an hour. Although the Consultant Anaesthetist made some attempt at providing pain relief, it might have been apparent that the relatively short duration of the block indicated it was not as effective. Medical Adviser 2 therefore concluded that because the block was not as dense as it should have been, there should have been a lower threshold for taking account of patient feedback and because the operation took longer than expected and did not go as planned, they would have expected an earlier recourse to convert to general anaesthetic. That said, this was a significant step to take given that Mr C was not necessarily in the best position and inducing anaesthesia might have compromised the sterile operating area. While Medical Adviser 2 could

understand the reticence and the attempt to comply with Mr C's expressed wish to avoid a general anaesthetic, on balance, they believed that there should have been an earlier heavy sedation or general anaesthetic provided.

(a) Decision

17. Mr C complained that the Board failed to provide a reasonable standard of hip replacement surgery. In reaching my decision, I have taken into account Mr C's clinical records and his account of what happened. Medical Adviser 1 said that the standard of surgery was reasonable and that the difficulties encountered did not amount to any clinical failings. I accept that advice. That is not to say that I underestimate how distressing Mr C's experiences were, and it is clear there were consequences in relation to anaesthesia and leakage of cement. In relation to anaesthesia, Medical Adviser 2's view is that Mr C experienced more pain and was uncomfortable for over an hour until the Consultant Anaesthetist administered a general anaesthetic, and it would have been reasonable if general anaesthetic had been undertaken earlier. Having considered matters carefully, my findings are that the evidence from the clinical records showed that while the surgical aspects of the operation were reasonable, there were shortcomings in relation to the provision of anaesthesia. Therefore, on balance, I uphold the complaint.

(a) Recommendation

18. I recommend that the Board:	*Completion date*
(i) bring Medical Adviser 2's comments in relation to anaesthesia to the attention of relevant staff.	22 July 2016

(b) Hospital staff failed to provide Mr C with appropriate anti-coagulant therapy following the surgery

19. Mr C said that he only received the normal therapeutic dose of heparin for four days following surgery when he had a family history of DVT, which was unreasonable, and that post-operative pain relief was also unreasonable.

The Board's response

20. The Board said that at the pre-assessment clinic on 27 November 2013 a VTE risk scoring form was completed and there was no record of a family history of VTE. The Consultant Surgeon requested that a heparin (a class of anticoagulant medications) was to be used and this was prescribed when Mr C was an in-patient. When Mr C was discharged (on 8 February 2014) post-operative VTE prophylaxis was discussed with the on call register who

advised that he should be discharged on aspirin (150 milligrams once daily for six weeks).

21. In response to my complaints reviewer's enquiries to the Board, the Consultant Surgeon said they had recorded in Mr C's operation note that enoxaparin (anticoagulant medication to treat or prevent blood clots and their complications) was to be used post-operatively, but it appeared that the on-call registrar made a decision (without consulting them) to send him home on aspirin instead. The Consultant Surgeon also told my complaints reviewer that it was common throughout Scotland for arthroplasty (surgery to relieve pain and restore range of motion by realigning or reconstructing a joint) patients to be given prophylaxis in the form of aspirin even though it was widely acknowledged by arthroplasty surgeons (in Scotland) that this was against SIGN and NICE guidelines. The Consultant Surgeon further explained that in the Hospital some of their colleagues used aspirin routinely in arthroplasty patients, but they had recorded that enoxaparin (in line with guidelines) was to be used in this case and that it was their routine policy for patients to be given six weeks of enoxaparin post-operatively following hip arthroplasty.

22. My complaints reviewer raised what the Consultant Surgeon said about the use of aspirin by surgeons with the Board. The Board's Medical Director responded that all hospital in-patients should receive risk assessment and treatment for VTE prophylaxis according to their protocol and if a clinician deviated from this on an individual basis, they should be able to explain and justify their decision. Also, that the Board did not have a specific policy on continuing prophylaxis post discharge apart from the requirement to indicate the need for it to be continued or otherwise to the patient's GP, and that the Consultant Surgeon had explained their personal policy in that regard for post-operative hip arthroplasty patients.

23. Regarding Mr C's concerns about post-operative pain relief, the Board explained that unfortunately he had fallen into the five percent of patients who have on-going hip pain despite having a stable total hip replacement. A potential cause of the pain was the excess cement at the joint but clinical opinion was that on balance it was better to leave this in place for now and that the pain would settle with time. Given that Mr C continued to have pain, he was referred to a consultant radiologist for an ultrasound scan for the possibility of aspiration (a procedure to remove fluid) to rule out the possibility of infection as the cause of his on-going pain.

Medical advice

24. In relation to the anti-coagulant therapy provided following the operation, Medical Adviser 1 said that Mr C should have received a combination of chemical and mechanical prophylaxis whilst he was an in-patient in line with relevant guidelines. Mr C was prescribed and received heparin which satisfied the requirement for chemical prophylaxis (and pneumatic boots were applied during surgery which satisfied mechanical prophylaxis), and there was an indication in the clinical notes of mechanical prophylaxis up to (and including) 8 February 2014. Medical Adviser 1 concluded, therefore, that Mr C received adequate prophylaxis up to (and including) 8 February 2014. (Medical Adviser 1 noted that all patients undergoing hip replacements were high risk and that the family history and length of surgery were not factors to be taken into account.) On discharge, Mr C should have received extended prophylaxis but he was given aspirin contrary to the guidelines. Medical Adviser 1 concluded that Mr C did not receive VTE prophylaxis in line with the guidelines and, likely as a consequence, suffered a pulmonary embolism. The Board therefore needed to review its standard operating procedure with regard to VTE prophylaxis to ensure it was in line with the guidelines. My complaints reviewer also asked Medical Adviser 1 about the Board's response to their enquiry about the Consultant Surgeon's statement on the use of aspirin and they said that sometimes guidelines were not followed if there was good reason (and the rationale was clearly recorded in the patient's clinical notes), but in this case there were no publications of scientific evidence indicating that aspirin was an acceptable form of DVT prophylaxis.

25. Turning now to whether Mr C's pain was managed in a reasonable way following the operation, Medical Adviser 1 outlined the pain relief given saying that he received regular paracetamol and slow release morphine tablets which was topped up with a quick acting liquid morphine. Medical Adviser 1 said that the initial regime should have produced sufficient analgesia but that the observation chart indicated significant pain up to late on 6 February 2014 and therefore the prescribed analgesics were increased. On discharge, the clinical records indicated that Mr C's pain was controlled and Medical Adviser 1 said that the prescription for on-going pain relief covering the first week after discharge was reasonable (and further responsibility for his medication thereafter passed to Mr C's general practitioner). Medical Adviser 1 concluded that clearly Mr C's pain was difficult to manage over the first few days after surgery, but that the treatment given seemed entirely appropriate.

(b) Decision

26. Mr C complained that the Board failed to provide him with appropriate anti-coagulant therapy following the surgery and that the pain relief was inadequate. Turning first to pain relief, the advice I have accepted is that while Mr C's pain was difficult initially to manage following surgery, the regime was appropriate and medical staff acted reasonably to increase his levels of pain relief. I also note Medical Adviser 1's comments that reasonable arrangements were made to manage Mr C's pain in the community before responsibility for the medication passed to his general practitioner. Taking all the evidence available to me into account, I consider that the treatment provided to manage Mr C's pain was reasonable.

27. Turning now to the anticoagulant therapy provided, Medical Adviser 1 said that Mr C did not receive VTE prophylaxis in line with the guidelines and that it was likely his pulmonary embolism was attributable to this. I accept that advice. My findings are that the failure to follow the guidelines led to a significant injustice to Mr C in that he suffered a life-threatening condition which required another admission to hospital for treatment. I am very concerned that the relevant guidelines were not followed in this case, particularly in light of the Board's poor response to the Consultant Surgeon's statement about the use of aspirin as a VTE prophylaxis. It remains unclear to me if the Board have a coherent policy that is being followed within the Hospital and beyond. As a result, an urgent review of the surgical practice in relation to VTE prophylaxis is required to ensure that Board surgeons are acting in line with the guidelines. I also intend to write to the Chief Medical Officer to draw their attention to my concerns about the use of aspirin and its potential implications for patient safety - particularly within the Hospital but possibly wider than that - which have come to light in the course of my investigation. I uphold the complaint.

(b) Recommendations

28. I recommend that the Board:	*Completion date*
(i) review as a matter of urgency the practice to ensure that its surgeons take into account the relevant guidelines on VTE prophylaxis;	22 August 2016
(ii) review its standard operating procedures concerning VTE prophylaxis for patients on discharge taking into account the relevant guidelines; and	22 July 2016

(iii)	apologise to Mr C for the failures this investigation identified.	22 July 2016

29. The Board have accepted the recommendations and will act on them accordingly. We will follow-up on these recommendations. The Board are asked to inform us of the steps that have been taken to implement these recommendations by the date specified. We will expect evidence (including supporting documentation) that appropriate action has been taken before we can confirm that the recommendations have been implemented.

Annex 1

Explanation of abbreviations used

Mr C	the complainant
the Hospital	Raigmore Hospital
the Board	Highland NHS Board
Medical Adviser 1	an adviser to the Ombudsman who specialises in orthopaedic surgery
Medical Adviser 2	an adviser to the Ombudsman who specialises in anaesthetic
the Consultant Surgeon	a consultant surgeon who works at the Hospital
the Consultant Anaesthetist	a consultant anaesthetist who works at the Hospital
SIGN	Scottish Intercollegiate Guidelines Network
VTE	venous thromboembolism
DVT	deep vein thrombosis
NICE	National Institute for Health and Care Excellence

Annex 2

Glossary of terms

anticoagulant medications	treatment with drugs that reduce the body's ability to form clots in the blood
arthroplasty	surgery to relieve pain and restore range of motion by realigning or reconstructing a joint
prophylaxis	a measure taken to maintain health and prevent the spread of disease
pulmonary embolism	a clot in the blood vessel that transports blood from the heart to the lungs
venous thromboembolism	the formation of blood clots in the vein