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: West of Scotland

Case ref: 201406803, Golden Jubilee National Hospital
Sector: Health
Subject: Hospitals; clinical treatment; diagnosis

Summary
Mrs C attended the Golden Jubilee Hospital for a modified Brostrom procedure (ligament repair) on her ankle. Following surgery, tests showed she had severe nerve damage. This was believed to have been caused by the popliteal nerve block anaesthesia (an injection of local anaesthetic near the nerves that go to the area being operated on) that she received for the surgical procedure. Mrs C complained that she was not informed the nerve block would be carried out or about the risks. She said that she did not see the consultant anaesthetist before the procedure. Mrs C complained that her injury was caused during the procedure and that staff failed to carry out the procedure to a reasonable standard. She said that the nerve damage had had an enormous impact on her life.

As part of my investigation, I obtained independent advice from a medical adviser who is a consultant anaesthetist. The adviser said there was no documented evidence in Mrs C's medical records of a discussion about the surgical procedure and its possible side effects, whether common but minor side effects, or rare but serious ones. The adviser noted that the General Medical Council (GMC) guidance on consent issues was clear that patients must be told about recognised serious adverse outcomes, even if they are rare. Nerve damage was a recognised side effect of techniques such as the nerve block so, even though the risk of permanent nerve damage was very rare, I considered it a failing that Mrs C was not warned about it. The limited interaction with Mrs C before her operation meant that staff did not obtain her informed consent and I upheld her complaint. I was concerned that these failings may have been caused by the pressures on the service. I recommended the board conducted a review to ensure enough time was spent with patients before procedures to obtain consent properly.

Regarding Mrs C's complaint that the procedure was not carried out properly, the adviser noted that there was no record taken at the time of the procedure of the anaesthetist's technique and practice. This was a significant failing. However, the adviser said the technique reported later (although without much

detail) gave an indication of a reasonable technique by an experienced clinician. I agreed with the advice that there was limited documentary evidence to indicate that the practice and technique was of a reasonable standard. Although there was no clear evidence that Mrs C's injury was caused during the procedure due to a failure by staff, the lack of contemporary record-keeping meant there was no assurance of carefully considered practice and technique. On balance, I upheld the complaint.

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) bring the failings (related to explaining the risks of a popliteal nerve block anaesthesia) to the attention of relevant staff and ensure they are raised as part of their annual appraisal;	23 April 2016
(ii) review the service to ensure there is sufficient time to properly obtain (and document) consent for procedures;	23 June 2016
(iii) bring the record-keeping failings (related to carrying out the procedure in an appropriate manner) to the attention of relevant staff and ensure they are raised as part of their annual appraisal; and	23 April 2016
(iv) apologise to Mrs C for the failures my investigation identified.	23 April 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 Mrs C. The terms used to describe other people in the report are explained as they arise and in Annex 1.

Introduction

1. Mrs C complained to the Ombudsman that she had not been informed she would be given a popliteal nerve block anaesthesia (an injection of local anaesthetic near to the nerves which go to the area of the operation) for a ligament repair or told of the potential complications and that the procedure caused permanent nerve damage.

2. The complaints from Mrs C I have investigated are that hospital staff failed to:

(a) explain the risks of a popliteal nerve block anaesthesia (*upheld*); and
(b) carry out the procedure in an appropriate manner (*upheld*).

Investigation

3. In order to investigate Mrs C's complaint, my complaints reviewer examined all the information provided by Mrs C. They also reviewed a copy of Mrs C's clinical records and the Golden Jubilee National Hospital (the Board)'s complaint file. Finally, they obtained independent advice from an experienced consultant anaesthetist adviser (the Medical Adviser) on the clinical aspects of the complaint and considered the General Medical Council (GMC)'s guidance on consent. In this case, we have decided to issue a public report on Mrs C's complaint because the failings I found led to a significant personal injustice to Mrs C, and to highlight the need to obtain properly informed consent before procedures are undertaken and disseminate the learning from this case to other health boards who provide similar services.

4. 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.

Relevant guidance and standards

5. The General Medical Council publishes national guidance on consent issues for registered doctors. Their publication entitled 'Consent Guidance: Discussion side effects, complications and other risks' (the GMC guidance) states that:

> 'In order to have effective discussions with patients about risk, you must identify the adverse outcomes that may result from the proposed options ...
>
> Risks can vary from common but minor side effects, to rare but serious adverse outcomes possibly resulting in permanent disability or death …

> You must tell patients if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small. You should also tell patients about less serious side effects or complications if they occur frequently, and explain what the patient should do if they experience any of them. (An adverse outcome resulting in death, permanent or long-term physical disability or disfigurement, medium or long-term pain, or admission to hospital; or other outcomes with a long-term or permanent effect on a patient's employment, social or personal life.)'

6. The Royal College of Anaesthetists' patient information leaflet on nerve damage associated with peripheral nerve block stated that the anaesthetist would discuss the benefits, risks and the patient's preferences before the patient decided whether to proceed with the nerve block. It also said that nerve damage could arise, amongst other things, due to direct injury caused by the needle (or the catheter) but that permanent nerve damage was very rare (temporary nerve damage was common and patients recovered within a few days or weeks).

7. The Association of Anaesthetists safety booklet[1] stated that pre-operative services should:

> 'ensure every patient was fully informed about the proposed procedure and interventions required; estimate the level of risk for every patient; and ensure every patient understood their own individual risk so that they could make an informed decision about whether to proceed to surgery.'

Background

8. Mrs C attended the Golden Jubilee Hospital for a modified brostrum procedure (ligament repair) on her right ankle on 27 November 2013. Following surgery, nerve conduction tests showed she had severe damage to her peroneal nerve and the tibual nerve, believed to have been caused by the popliteal nerve block that she received for the surgical procedure.

(a) Hospital staff failed to explain the risks of a popliteal nerve block anaesthesia

9. Mrs C complained that she was not informed the nerve block would be carried out or about the risks and said that she did not see the consultant anaesthetist (the Consultant Anaesthetist) before the procedure. Mrs C said the

[1] The Role of the Anaesthetist Preoperative Assessment and Planning 2010

nerve damage she suffered as a result has had an enormous impact on her life including her mobility and being medically retired.

The Board's response

10. The Board said that the Consultant Anaesthetist recalled Mrs C was admitted to the day surgery unit which was a busy environment in which patients saw the surgeon, anaesthetist and nursing staff in quick succession before surgery. The Consultant Anaesthetist highlighted that in this environment it could be particularly challenging not to overwhelm patients with jargon whilst ensuring that the patient was sufficiently informed about the plans and options for their care. Moreover, the Consultant Anaesthetist would not use the term 'popliteal block' (rather, they would explain what the procedure entailed in plain English with a demonstration and would ask if patients were happy with this). The Board apologised if this was not explained clearly - the risks of permanent damage were extremely low (0.002 percent) so they would not have specifically mentioned it but would focus on more common risks – and there had been no complications in Mrs C's case, although the nerve may have been struck inadvertently by the anaesthetic needle. The Board apologised if the Consultant Anaesthetist did not provide sufficient information on this occasion. The Board explained that such complications do not always have an obvious cause and they outlined the detailed steps they had taken as a result of this incident including providing patient information sheets about peripheral nerve blocks before procedures and continuous training etc.

11. In response to Mrs C's further concerns that she did not see the Consultant Anaesthetist before the procedure, the Board explained that the Consultant Anaesthetist had provided general comments about their routine practice but did not specifically recall speaking to Mrs C given the time elapsed. The Board apologised and said that error occurred because Mrs C was initially listed wrongly for local anaesthetic and not general anaesthetic and she was not seen by an anaesthetist prior to surgery. Despite this, the Board reiterated that their normal practice would not have been to have raised this complication in any event.

The Consultant Anaesthetist's account

12. The Consultant Anaesthetist had discovered that the theatre list on the day of Mrs C's surgery placed her first on the list, and planned for local anaesthetic technique. This was not appropriate for the extensive surgery planned. This clerical error would have caused Mrs C not to have been seen by

an anaesthetist before the procedure. The Consultant Anaesthetist may have spoken to Mrs C in the pre-operative waiting area but they could not be certain whether this occurred. It was therefore possible that Mrs C went to theatre without the required explanation for her planned pain management (popliteal nerve block) or that the environment and Mrs C's stress levels immediately prior to surgery would have negated any explanation given. They also outlined their training and experience in administering nerve blocks.

Medical advice

13. The Medical Adviser said that the popliteal nerve block performed on 27 November 2013 was part of the anaesthetic technique and post-operative analgesia for foot surgery and that GMC guidance and relevant standards were clear around consent, therefore, it was not sufficient to use the reason of 'information overload' to spare patients the opportunity to give informed consent. The Medical Adviser noted that there was no evidence of any discussion with Mrs C about the procedure and its possible side-effects; there was no documented discussion of any kind including more common side-effects such as transient pain, haematoma or local infection (or even failure) that should have been discussed with Mrs C. Moreover, the Medical Adviser said that nerve damage was an accepted side effect of regional techniques such as this type of 'block', although permanent nerve damage was far rarer but the lack of any discussion of any level of nerve damage was a failing. The Medical Adviser concluded that if the service was so busy that it risked effective and meaningful engagement with patients before operations to explain techniques, risks and to provide reassurance then the service needed significant revision. The limited interaction with Mrs C before the operation was clearly a failing and one that the Board needed to address.

(a) Decision

14. Mrs C complained that Board staff had failed to explain the risks of the nerve block. In reaching my decision, I have considered Mrs C's account of what happened and the advice I have received. The Medical Adviser said there was no documented discussion of any kind about the procedure and its possible side-effects which was a failing. I accept that advice. Moreover, Mrs C said that she did not even see the Consultant Anaesthetist before the procedure and I note the Board acknowledged this. These failings are concerning and led to a significant injustice to Mrs C in that clinicians failed to obtain her informed consent for the procedure. Whilst the risk of permanent nerve damage occurring is very small, given the GMC's guidance that patients must be told

about recognised serious adverse outcomes, even if they are rare, I consider that Mrs C should have been warned of this potential adverse outcome. I uphold the complaint. I am also concerned that the failings in this case may have arisen due to the pressures on the service and recommend that the Board carry out a review to ensure there is sufficient time to obtain consent properly in addition to a further recommendation to address the failings. As part of their review, the Board should also consider their consent form to ensure that discussions between patients and clinicians about possible risks and complications - including serious adverse outcomes even if they are rare - are clearly recorded.

(a) Recommendations

15. I recommend that the Board:	*Completion date*
(i) bring the failings to the attention of relevant staff and ensure they are raised as part of their annual appraisal; and	23 April 2016
(ii) review the service to ensure there is sufficient time to properly obtain (and document) consent for procedures.	23 June 2016

(b) Hospital staff failed to carry out the procedure in an appropriate manner

16. Mrs C complained that her injury was caused during the procedure and that staff failed to carry out the procedure to a reasonable standard.

The Board's response

17. The Board said that there had been no complications, although the nerve may have been struck inadvertently by the anaesthetic needle.

Medical advice

18. The Medical Adviser noted there was no contemporaneous account of the Consultant Anaesthetist's technique in the copy of clinical records provided by the Board. If a contemporaneous record did not exist, this was a failing and did not give assurance of good practice. The Medical Adviser explained that the techniques used included ultrasound guidance in conjunction with or without a peripheral nerve stimulator. The Consultant Anaesthetist said that they had long experience of this technique; the Medical Adviser concluded that the Consultant Anaesthetist did not use a peripheral nerve stimulator but said that that in itself was not a failing as evidence suggested there was always a

residual risk of the injury and use of ultrasound guide or peripheral nerve stimulator did not completely eliminate complications. It was not clear from the available evidence if Mrs C had been anaesthetised prior to establishing the block (there was indirect evidence of the efficacy of the block from the brief period in the covered area where Mrs C was noted as being comfortable). The main advantage of a patient being aware during insertion of a block is eliciting various stimuli if a nerve was approached and a pain free injection was always considered safer. When a patient's response was masked by anaesthesia, these responses were lost. However, the Medical Adviser said there were many variations and different approaches and the technique described in Mrs C's clinical notes while not particularly detailed, gave an indication of a reasonable technique by an experienced clinician. The Medical Adviser reiterated that there was always a risk of complication even in technically perfect injections.

19. In conclusion, the Medical Adviser said the reported technique in the Consultant Anaesthetist's statement was one that would be used by an experienced clinician, but that the absence of contemporary record-keeping (failure to record the anaesthetic) failed to provide assurance of a careful considered practice and technique in this instance (although the Medical Adviser reiterated that nerve damage has resulted in even uncomplicated blocks).

(b) Decision

20. Mrs C complained that staff failed to carry out the procedure to a reasonable standard. In reaching my decision, I have taken into account Mrs C's clinical notes and the advice I have received. The Medical Adviser said there was limited documentary evidence to indicate that the practice and technique in this instance was of a reasonable standard. I agree with the Medical Adviser that this was a significant failing. The advice I have accepted is that nerve damage can result even in uncomplicated blocks and that there is no clear evidence that Mrs C's injury was caused during the procedure due to a failure by staff. Having said that, given the absence of a contemporary record of the operation, on balance, I uphold the complaint.

(b) Recommendations

21. I recommend that the Board:	*Completion date*
(i) bring the failings to the attention of relevant staff	23 April 2016

and ensure they are raised as part of their annual appraisal; and

(ii) apologise to Mrs C for the failures my investigation identified. — 23 April 2016

22. 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

Mrs C	the complainant
the Hospital	the Golden Jubilee National Hospital
the Medical Adviser	an adviser to the Ombudsman who specialises in anaesthetics
GMC	General Medical Council
the Anaesthetist Consultant	an anaesthetist consultant at the hospital

Annex 2

Glossary of terms

popliteal nerve block anaesthesia	an injection of local anaesthetic near to the nerves which go to the area of the operation
modified bostrom procedure	ligament repair

Annex 3

List of legislation and policies considered

GMC - Consent Guidance: Discussion side-effects, complications and other risks