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: South of Scotland

Case ref: 201508192, Ayrshire and Arran NHS Board
Sector: Health
Subject: Hospitals / Clinical treatment / Diagnosis

Summary
Mrs A complained about the care and treatment she received from the board. Mrs A died before I completed my investigations and so her complaint was taken on by her daughter (Mrs C).

Mrs A attended University Hospital Crosshouse. She was told that she may need a heart valve replacement but that before this could go ahead, she would need to undergo a cardiac angiogram (a type of x-ray used to examine blood vessels), which is an invasive procedure. Mrs A gave consent and underwent an angiogram in a second hospital run by the board. Mrs A said that she experienced pain during the procedure and asked for it to be stopped. The procedure continued but Mrs A did not recover well and while no abnormality was obvious, her condition did not improve. Mrs A's level of consciousness declined and a few days later she was noted to have lost power in her lower limbs. A scan of her spine showed evidence of an ischaemic event (like a stroke) within her spinal cord.

Mrs A was transferred to a third hospital (in a different NHS board), where her scan was reviewed. This showed the appearance of a stroke on the surface of the brain. Mrs A did not recover the use of her lower limbs.

Mrs A complained that she had not been warned of the possible risks associated with an angiogram. She also complained of an unreasonable delay in confirming a stroke and that as a result her treatment was delayed.

The board said that Mrs A had made informed consent for the procedure and recognised that there had been a delay in diagnosis. They added that even if a stroke had been confirmed sooner, it was unlikely there would have been a different outcome regarding surgery or spinal cord recovery.

I took independent advice from a consultant cardiologist and from a consultant neuroradiologist (a specialist in the analysis of injuries of the brain). The advisers found no evidence that all the risks and benefits of an angiogram had

been discussed with Mrs A, including that bleeding and vascular damage that could cause a possible stroke or heart attack are a recognised complication. I also found the board's consent forms and printed information to have been inadequate. I established that there was an error in interpreting Mrs A's scan and that her diagnosis had been delayed, although Mrs A's treatment and outcome were likely to have been the same had an earlier diagnosis been made. I therefore upheld the complaint.

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) make a formal apology to Mrs C for their failure to consent Mrs A properly;	30 September 2016
(ii) review their consenting procedure and update it in accordance with General Medical Council guidelines. They should demonstrate to me that they have done so;	30 September 2016
(iii) review their relevant information booklet/sheet to ensure that they reflect the appropriate guidelines; and	31 October 2016
(iv) apologise to Mrs C for the delay in Mrs A's diagnosis.	30 September 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 A complained to the Ombudsman about the care and treatment she received from Ayrshire and Arran NHS Board (the Board). The complaints I have investigated are that:

(a) the Board did not reasonably tell Mrs A about the possible risks associated with an angiogram procedure before consent was sought (*upheld*); and

(b) there was an unreasonable delay in diagnosing stroke and beginning treatment *(upheld).*

Before a draft of this report was issued for consideration, Mrs A died. Her daughter (Mrs C) continued the complaint on her behalf.

Investigation

2. In order to investigate the complaint, my complaints reviewer considered all the complaints correspondence and Mrs A's relevant medical records. They also took into account General Medical Council (GMC) guidelines on the process of consenting and obtained independent advice from consultants in cardiology (Adviser 1) and neuroradiology (Adviser 2). I have decided to issue a public report due to the injustice suffered by Mrs A and my concerns about the Board's procedure for obtaining consent.

3. This report does not include 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.

Background

4. On 28 February 2014, Mrs A attended a Valve Clinic at University Hospital Crosshouse in Kilmarnock (Hospital 1), when it was explained to her that, in view of her presenting symptoms, she was likely to need an aortic (heart) valve replacement. However, before this could go ahead, she would require assessment by way of a cardiac angiogram (a type of x-ray used to examine blood vessels). A catheter is inserted through a small incision into a blood vessel and then into the heart using x-ray guidance. A small amount of dye is injected. Mrs A gave consent for the procedure the same day and underwent an angiogram at University Hospital Ayr (Hospital 2) on 12 March 2014. Mrs A said that during the procedure she experienced pain and asked that it be stopped but that the surgeon continued.

5. Mrs A did not recover well and complained of headaches and back pain. No cardiovascular abnormality was obvious but her condition did not improve and two hours after the operation her Glasgow coma scale (GCS, a scale for recording the conscious state of a person) was 10/15. The lower the score out of 15, the lower the patient's conscious state. An urgent computerised tomography (CT) scan was carried out but the consultant radiologist reported no abnormality.

6. The next day, Mrs A's GCS had improved to 12/15 but she was unable to fully cooperate with a physical examination. While her GCS score normalised on 14 March 2014, she was noted to have lost power in her lower limbs. A magnetic resonance imaging (MRI) scan of her spine was performed, which showed evidence of an ischemic event (like a stroke) within her spinal cord. Mrs A was then transferred to the neurological team at the Southern General Hospital in Glasgow (Hospital 3), who reviewed the CT scan which had been carried out in Hospital 2 and reported the appearance of a subarachnoid haemorrhage (an uncommon type of stroke caused by bleeding on the surface of the brain). Mrs A remained in Glasgow for two weeks after which she was transferred to Hospital 1. She did not recover the use of her lower limbs.

7. Mrs A complained that the Board did not inform her fully of the risks associated with the procedure before obtaining her consent. She also complained that there was an unreasonable delay in diagnosing her as having had a stroke and thus providing her with treatment.

8. A formal complaint was made to the Board in September 2014 and the Board responded in February 2015. A further letter was sent to Mrs A in June 2015. Essentially, the Board said that Mrs A had made informed consent for the procedure although they recognised that there had been a delay in diagnosing her. However, they added that even if a stroke had been confirmed sooner, it is unlikely there would have been a different outcome regarding surgery or spinal cord recovery.

(a) The Board did not reasonably tell Mrs A about the possible risks associated with an angiogram procedure before consent was sought

9. Adviser 1 told me that Mrs A was seen at a heart valve clinic in Hospital 1 in February 2014 as part of a regular review. She had symptoms of breathlessness, chest pain and a sensation that she might faint. I understand that these were all clinical features known to be related to severe obstruction of

one of the main heart valves. As an operation to treat her condition was being considered, further tests were indicated.

10. A consultant cardiologist (Doctor 1) advised Mrs A that further investigation with coronary angiography would be appropriate. This was a routine, invasive x-ray test to show the main blood vessels to the heart muscle. The same day, Mrs A was placed on a waiting list for the procedure, with the request that it be 'soon'. She also signed a consent form that day and was provided with written information about the test (a leaflet and an information sheet).

11. The procedure was undertaken by different consultant cardiologist (Doctor 2) on 12 March 2014 and Mrs A said that she complained of chest discomfort during the angiogram, although no complications were noted during the procedure. She subsequently complained of headache, back and chest pain. Because of a falling conscious level, a CT brain scan was considered at 19:55 and undertaken at 21:20. Whilst the result was initially felt to be normal, it was subsequently shown to demonstrate a subarachnoid haemorrhage. An MRI scan taken on 14 March 2014 showed an injury to Mrs A's upper spinal cord, resulting in a loss of power to her lower limbs, and she was transferred to the neurological centre in Hospital 3.

12. Mrs A complained that she had not been not properly consented before her operation and Adviser 1 confirmed that this matter was the subject of GMC guidelines where it made clear that the risks and benefits of any procedure or course of treatment should be explained, including those related to having any alternative treatment as well as having no treatment at all. In terms of detailing the risks, the GMC guidelines indicate that the information given should include what a patient would reasonably expect to know in order to be able to make an informed choice.

13. Adviser 1 said that the recognised complications of coronary angiography included bleeding from the arterial access site (which may require surgical repair), vascular damage causing a possible stroke or heart attack, an allergic reaction to the contrast agent used (dye), and death. They added that the quoted incidence of such complications lay in the region of one 1 in 700 to 1 in a 1,000. With regard to Mrs A's case, Adviser 1 said that the review of her case notes led them to the conclusion that there was no evidence that the process had been followed. Specifically, that the correspondence and hand-written note

entry relating to the clinic visit (and to the formal taking of consent) on 28 February 2014 did not provide documented evidence to indicate that these risks had been discussed with Mrs A.

14. Adviser 2 agreed and said that while consent was sought well in advance of the procedure (as was good practice), there were no contemporaneous notes to confirm that the risks noted (see paragraph 13) were discussed. They added that the risks of heart attack, stroke, possible need for cardiac surgery and even death were not mentioned in the consent form, clinical notes or in the information pamphlet and sheet. With regard to this, Adviser 1 said that, in terms of current practice, the consent form was inadequate. While it documented that the 'nature and purpose' of the procedure had been explained, it did not mention, itemise or quantify any risks, nor did it indicate the alternative treatment or options and that each of these had been discussed.

(a) Decision

15. The advice received from both Advisers 1 and 2 was that, contrary to GMC guidelines, not all the risks, including that of a stroke, were discussed with Mrs A before her angiogram. Nor were they mentioned in the written information she received. For this reason, I uphold the complaint. It was entirely possible that Mrs A, knowing the seriousness of her heart condition, would have given her consent, not withstanding the risks, but she was entitled to make her decision in full knowledge of the facts. This was denied to her.

16. The Board should, therefore, make a formal apology to Mrs C for their failure to consent Mrs A properly. They should also review their consenting procedure and update it in accordance with GMC guidelines and they should demonstrate to me that they have done so. Furthermore, they should review their relevant information booklet/sheet to ensure that they reflect the appropriate guidelines.

(a) Recommendations

17. I recommend that the Board:	*Completion date*
(i) make a formal apology to Mrs C for their failure to consent Mrs A properly;	30 September 2016
(ii) review their consenting procedure and update it in accordance with GMC guidelines. They should demonstrate to me that they have done so; and	30 September 2016

(iii)	review their relevant information booklet/sheet to ensure that they reflect the appropriate guidelines.	31 October 2016

(b) There was an unreasonable delay in diagnosing stroke and beginning treatment

18. Mrs A said that when her operation began, she experienced discomfort and asked Doctor 2 to stop but that, nevertheless, the operation continued. She then said that complications arose while she was undergoing the angiogram and she was unconscious for days afterwards. She did not remember being transferred to Hospital 3, where she remained for some weeks. Mrs A said that it was only after she went to Hospital 3 that she learned she had suffered a stroke and she believed that time had been lost in making her diagnosis, as a consequence of which there was a delay in treating her appropriately.

19. Mrs A complained to the Board. They replied on 2 February 2015. They explained that during the procedure, a patient could sometimes develop spasm of the artery which could cause discomfort in the upper chest, arm or back and that if pain occurred, the accepted practice was to pause to allow the discomfort to settle or to give additional treatment if required. Occasionally, the procedure would be terminated if the spasms became too severe and a judgement would have to be made about what would be in the patient's best interest and whether or not to continue. In Mrs A's case, the Board said that Doctor 2 felt that Mrs A's discomfort had settled enough and that he should, therefore, complete the process.

20. Adviser 1 confirmed that it was not uncommon for patients to feel discomfort and that this could relate to the arterial puncture site in the arm (as in Mrs A's case). They added that it would be very rare for the surgeon to feel unable to continue with the procedure because of such symptoms. Adviser 1 said that the decision made would be taken in the best interests of the patient and confirmed their view that, in the circumstances, Doctor 2 had acted reasonably. Adviser 2 agreed.

21. Adviser 1 said that Mrs A's operation was concluded at 15:25 but at 17:10, because of symptoms of headache, vomiting and a reduced level of consciousness, a CT brain scan was considered. It was requested at 19:55. Adviser 2 said that it was reasonable initially to conclude that Ms A's pain was due to vascular spasm and the headache, which came on later, was related to nitrates which had been given for the spasm. Two hours later, Mrs A's GCS

had reduced to 10/15 or less and she had difficulty in describing her symptoms; meanwhile her pain was continuing. Adviser 2 said that it was, therefore, correct and prudent to pursue a CT examination of her head and of her aorta to exclude arterial dissection, which could have accounted for Mrs A's severe back pain. Adviser 2 said that the CT scan was performed at 21:17, following an injection of dye to highlight Mrs A's blood vessels in order to look for vascular damage. Although her chest and aorta were normal, the presence of the dye made it more difficult to detect the subarachnoid haemorrhage (bleeding into the fluid surrounding the brain).

22. Adviser 2 commented that the following morning, Mrs A's GCS had improved to 12 but she was not able to fully cooperate with a physical examination. Other diagnostic possibilities, including infection and a reaction to the dye, were considered and they said that appropriate treatment was given.

23. On 14 March 2014 (36 to 48 hours later), Mrs A's GCS had recovered to 15 but clinical examination revealed paraplegia (weakness/paralysis of Mrs A's lower limbs). An MRI scan of her spine was undertaken and this showed a subdural (outside the spinal cord) haematoma (blood clot) at the lower part of her neck/upper part of the thoracic spine (upper/middle back). This haematoma was lying to the front and right of her spinal cord which was displaced due, presumably, Adviser 2 said, to ischaemia (interruption in the blood supply) and oedema (swelling caused by a build-up of fluid).

24. Adviser 2 stated that in their view, it was impossible to determine the time of the onset of the paraplegia as there may have been an interval between the haematoma and the development of oedema of the spinal cord.

25. Mrs A was then referred to the neurological team at Hospital 3 and, on reviewing the imaging, the presence of a subarachnoid haemorrhage was noted. Further imaging confirmed the absence of vascular abnormality in Mrs A's head, which could have accounted for the haemorrhage. Adviser 2 confirmed that the incidence of paraplegia as a complication of coronary/cardiac angiography was infinitely small, especially considering the number of procedures performed. Therefore, in their view it was very unlikely that Mrs A's spinal haematoma could be directly or mechanically related to the catheter procedure as there was no evidence of vascular damage, for example dissection, or of underlying vascular abnormality. They also said that it was unlikely that these two events were unrelated. Adviser 2 said that they were in

no doubt that an error in reporting was made as a haemorrhage was clearly present in the ventricles but had been a little more difficult to see over the brain convexity (surface).

26. Adviser 2 said that the exact reason for Mrs A's spinal haemorrhage was not clear. However, they strongly suspected that the spinal subdural haematoma could have been the source of the subacrachnoid haemorrhage spreading to the head. This in turn caused a reduction in Mrs A's conscious level, making it difficult to make a full clinical assessment and thus a delay in clinically appreciating the presence of paraplegia. Nevertheless, they went on to say that the initial error in interpreting the CT brain examination of 12 March 2014 had no detrimental outcome and even the delayed diagnosis of the spinal haematoma did not alter Mrs A's management or outcome.

27. Both advisers said that this was a very rare and tragic complication of the surgical procedure Mrs A underwent, which would have been impossible to predict or avoid. Adviser 1 said that it was not clear exactly what had caused the complication during the angiography but that some type of injury occurred which resulted in damage to the spinal cord. Adviser 1 believed that this was in all likelihood unavoidable but that the risk of stroke – even in the form of a recognised but unusual complication – did not appear to have been discussed with her.

(b) Decision

28. The advice I received was that there was an initial error in interpreting the CT scan undertaken on 12 March 2014. Similarly, there was a delayed diagnosis of the spinal haematoma. I therefore upheld the complaint. Nevertheless, Adviser 2 went on to say that, regardless of the delay, it was their view that Mrs A's treatment and outcome would have remained the same.

29. A fairly routine operation, which Mrs A needed, had a tragic outcome for her. She had my sincere sympathy. Regrettably, Mrs A's heart condition continued to decline and she died in November 2015. Her family have my condolences and the Board should now apologise to Mrs C for the delay that occurred in Mrs A's diagnosis. The Board have already informed my complaints reviewer that, as a consequence of this complaint, the radiology department has decided to adopt a more rigorous approach and obtain a pre-contrast examination of the brain, in the hope that this will make it easier to detect the

presence of haemorrhage in subarachnoid space and so I make no further recommendation in this regard.

(b) Recommendation

30. I recommend that the Board:	*Completion date*
(i) apologise to Mrs C for the delay that occurred in Mrs A's diagnosis.	30 September 2016

31. The Board have accepted the recommendations and will act on them accordingly. We will follow-up on these recommendations and the Board are asked to inform us of the steps taken to implement them by the date specified. We require 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 A	the aggrieved
Mrs C	The complainant
the Board	Ayrshire and Arran NHS Board
GMC	the General Medical Council
Adviser 1	a consultant cardiologist
Adviser 2	a consultant neuroradiologist
Hospital 1	University Hospital Crosshouse
Hospital 2	University Hospital Ayr
GCS	Glasgow coma scale
CT scan	A computerised tomography scan
MRI	Magnetic Resonance Imaging
Hospital 3	Southern General Hospital
Doctor 1	a consultant cardiologist
Doctor 2	a second consultant cardiologist

Annex 2

Glossary of terms

aortic	of the heart
arterial dissection	a tear in the artery
cardiac angiogram	a type of x-ray used to examine blood vessels. A catheter (tube) is inserted through a small incision into a blood vessel and then into the heart using x-ray guidance. A small amount of dye is injected
gaematoma	blood clot
ischaemia	interruption of the blood supply
ischaemic event	like a stroke
oedema	swelling caused by build-up of fluid
paraplegia	weakness/paralysis
subarachnoid haemorrhage	an uncommon type of stroke, caused by bleeding on the surface of the brain
subdural	outside the spinal cord
thoracic spine	the upper/middle back