SPSO Scottish Public Services Ombudsman

The Scottish Public Services Ombudsman Act 2002

Investigation Report

UNDER SECTION 15(1)(a)

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Scottish Parliament Region: Central Scotland

Case ref: 201507615, Lanarkshire NHS Board
Sector: Health
Subject: Hospitals / Clinical treatment / Diagnosis

Summary
Mr C's wife (Mrs A) was admitted by ambulance to Monklands Hospital with increased breathlessness. While visiting Mrs A, her daughter (Ms B) who is a nurse, reviewed Mrs A's medical records and noticed that it was recorded that Mrs A had been given Amoxicillin, a penicillin antibiotic, earlier in the day. Mr C said that he had made both ambulance and hospital staff aware that Mrs A was allergic to penicillin and that, previously, penicillin had caused Mrs A to suffer anaphylactic shock. Mr C said that thereafter Mrs A's condition deteriorated.

Mr C said that although Ms B had immediately informed a member of the nursing staff of the prescribing error, staff had failed to take corrective action and to conduct increased observations of Mrs A. Mr C said there was also a failure to document the incident in Mrs A's medical records at the time and again when Mrs A was later transferred to the Intensive Care Unit (ICU). Mr C believed there had been unreasonable delay in transferring Mrs A to the ICU where she remained until her death.

Mr C considered that Mrs A had been denied proper treatment for the possible adverse effects of an anaphylactic reaction to the Amoxicillin. Mr C said that he believed the error in administering Amoxicillin to Mrs A and the lack of an appropriate response could have hastened or brought about Mrs A's deterioration and death. As a result, Mr C believed that Mrs A had not been provided with a reasonable standard of care and treatment.

The board acknowledged that Mrs A was unreasonably prescribed and administered Amoxicillin when she had a known allergy; that the response of medical and nursing staff was deficient; and there were failures in record-keeping. The board said that, while Amoxicillin should not have been prescribed or administered to Mrs A, there was no suggestion that an allergic response was seen or was responsible for Mrs A's subsequent clinical course.

During the investigation, my complaints reviewer took independent advice from a consultant in respiratory medicine and a nurse.

Regarding Mr C's complaint that Mrs A was unreasonably given Amoxicillin when she had a known allergy to penicillin, the medical and the nursing advisers said that while what had occurred in Mrs A's case was a human error, the failure by staff to follow drug administration policies was a serious incident and represented serious failings in care.

In respect of Mr C's complaint that staff had failed to take appropriate steps when the prescribing error was reported to them, the medical adviser said that although the board had accepted there were failures in the response of nursing and medical staff to Mrs A wrongly being administered Amoxicillin, these failings fell below an expected standard of care that Mrs A should have received and represented serious failings in Mrs A's care.

Mr C also complained that there was a failure to provide Mrs A with a reasonable standard of treatment. The medical adviser said that the deterioration in Mrs A's condition was due to the worsening of an underlying condition and not to the administration of Amoxicillin. However, the medical adviser said there were missed opportunities to identify the severity of the deterioration in Mrs A's condition earlier on in her admission and Mrs A should have been referred earlier to the ICU team. All of which represented a serious failure in Mrs A's care. I accepted the advice I received.

I was concerned by the serious failings identified in Mrs A's care and treatment and in view of these failings, I upheld all of Mr C's complaints. I have, therefore, made recommendations to address this.

Redress and recommendations

The Ombudsman recommends that the Board:	*Completion date*
(i) apologise for the failings identified in complaint (a) in relation to the prescribing and administration of Amoxicillin when Mrs A had a known allergy to penicillin;	14 March 2017
(ii) ensure the comments of Adviser 1 and Adviser 2 in complaint (a) about the action that requires to be taken to avoid a repetition of what occurred are brought to the attention of relevant staff and to report back on the action taken;	14 April 2017

(iii)	carry out a review of the Action Plan and the Board's policies on drug administration in view of the comments of Adviser 1 and Adviser 2 referred to at paragraphs 31, 34 and 35 and to report back on the action taken;	14 April 2017
(iv)	provide my office with an update on the work of the Patient Safety Programme;	14 April 2017
(v)	apologise for the failings identified in complaint (b) in relation to the failure to take appropriate action when it was reported that Mrs A had wrongly being administered Amoxicillin;	14 March 2017
(vi)	ensure the comments of Adviser 1 and Adviser 2 in complaint (b) are brought to the attention of relevant staff and to report back on the action taken;	14 April 2017
(vii)	carry out a review of the Action Plan in view of the comments of Adviser 1 referred to at paragraph 55 and to report back on the action taken;	14 April 2017
(viii)	provide evidence to show how they encourage staff to report early when errors occur and how they share the learning from such errors with staff;	14 April 2017
(ix)	apologise for the failings in Mrs A's treatment identified in complaint (c);	14 March 2017
(x)	ensure the comments of Adviser 1 and Adviser 2 in complaint (c) are brought to the attention of relevant staff and to report back on the action taken; and	14 April 2017
(xi)	carry out a review of the Action Plan in view of the comments of Adviser 1 referred to at paragraphs 95; 96 and 97 and to report back on the action taken.	14 April 2017

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, and his late wife is Mrs A. 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 my office about the care and treatment his late wife (Mrs A) received while she was a patient in Monklands Hospital (the Hospital) between 26 December 2014 and 2 January 2015. Sadly, Mrs A died on 2 January 2015. The recorded cause of Mrs A's death was pulmonary oedema, chronic obstructive pulmonary disease (COPD), and refractory cardiovascular collapse.

2. Mrs A was admitted by ambulance to the Hospital's Emergency Department (ED) at 00:02 on 26 December 2014 with increased breathlessness. Mrs A had a history of asthma, COPD and angina. Mrs A was initially treated for an exacerbation of asthma/COPD and pulmonary oedema. She was subsequently admitted to the Emergency Receiving Unit (ERU) in the early hours of the morning of 26 December 2014 and then transferred to Ward 17, a respiratory ward, later the same day.

3. Mr C said that, during the evening visit to Mrs A on 26 December 2014, his daughter (Ms B) a nurse, reviewed Mrs A's medical records and noticed that it was recorded that Mrs A had been given Amoxicillin, a penicillin antibiotic, between 12:00 and 14:00 earlier in the day. Mr C said that he had told the ambulance staff transporting Mrs A to the Hospital and also the staff in the ED that Mrs A was allergic to penicillin. Mr C said that on two previous occasions penicillin had caused Mrs A to suffer anaphylactic shock.

4. Mr C said that Ms B immediately informed a member of the nursing staff of the error. However, according to Mr C, staff failed to take corrective action and to conduct increased observations of Mrs A. Mr C said there was also a failure to document the incident in Mrs A's medical records at the time and again when Mrs A was later transferred to the Intensive Care Unit (ICU) on 29 December 2014, where she remained until her death on 2 January 2015. Mr C said he also considered there had been unreasonable delay in transferring Mrs A to the ICU.

5. Mr C said that Mrs A had been denied proper treatment for the possible adverse effects of an anaphylactic reaction to the Amoxicillin which had been administered to her. Mr C said that he believed the error in administering Amoxicillin to Mrs A and the lack of an appropriate response could have hastened or brought about Mrs A's deterioration and death. Mr C considered that Mrs A had not been provided with a reasonable standard of treatment.

6. Mr C and members of his family met with representatives of Lanarkshire NHS Board (the Board) at meetings in January 2015 and July 2015 to discuss their concerns. Mr C remained dissatisfied with the Board's response and considered they had failed to learn lessons, so as to avoid a recurrence of what had happened to Mrs A. Mr C also considered the Board had failed to issue him and his family with an appropriate apology for what had happened to Mrs A.

7. The Board acknowledged that Mrs A was unreasonably prescribed and administered Amoxicillin when she had a known allergy; that the response of medical and nursing staff was deficient; and there were also failures in record-keeping. The Board also acknowledged that it had become apparent that the process concerning patients wearing a red allergy identification wrist band to highlight to staff the presence of an allergy had not been followed correctly.

8. The Board stated that, while Amoxicillin should not have been prescribed or administered to Mrs A, there was no suggestion that an allergic response was seen or was responsible for Mrs A's subsequent clinical course.

9. The complaints from Mr C I have investigated are that the Board:

(a) unreasonably gave Amoxicillin when Mrs A had a known allergy to penicillin (*upheld*);
(b) failed to take appropriate steps when this error was reported to them (*upheld*); and
(c) failed to provide a reasonable standard of treatment (*upheld*).

Investigation

10. The investigation of Mr C's complaint involved obtaining and examining all of the relevant documentation, including the complaints correspondence and Mrs A's medical records. Independent advice has been obtained from a consultant in respiratory medicine (Adviser 1) and a nurse (Adviser 2) on the clinical aspects of the complaint.

11. 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 Mr C and his family and because we considered the Board's own investigation had not fully acknowledged the seriousness of what happened in Mrs A's case, identified all the relevant learning and taken all necessary action to avoid a recurrence.

12. 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.

(a) The Board unreasonably gave penicillin when Mrs A had a known allergy

Concerns raised by Mr C

13. Mr C told us that Mrs A suffered from a number of health conditions, including asthma, COPD, and angina. On 25 December 2014 Mrs A experienced shortness of breath, coughing and difficulty talking at home. An ambulance was called and she was admitted to the ED shortly after midnight on 26 December 2014 with Mr C and other members of their family in attendance. Mr C said he made the ambulance staff and the medical staff in the ED aware of Mrs A's allergy to penicillin.

14. Mr C said that, following a chest x-ray, they were informed by the doctor treating Mrs A that she had been diagnosed with pulmonary oedema and she was admitted to the ERU and then later transferred to Ward 17.

15. Mr C said that he and his family visited Mrs A in Ward 17 on the evening of 26 December 2014. Mr C said that during the visit Mrs A had appeared settled, alert and she was mobile. Mr C said Ms B had read Mrs A's medical records to see what her mother's treatment plan was and noticed that Mrs A had been prescribed Amoxicillin, Clarithromycin and Prednisolone. It was recorded that Mrs A had been given 1 gram of Amoxicillin between 12:00 and 14:00. The allergy section in the drug Kardex, the patient's prescription chart, was blank and there was nothing documented about Mrs A's allergy to penicillin. Mr C and Ms B said, however, that Mrs A was wearing a red allergy identification wrist band when they visited her and this was before Ms B had raised the matter of Mrs A being given Amoxicillin with the nurse in charge of the ward.

The Board's response to Mr C

16. The Board said that Mrs A had arrived in the ED at 00:02 on 26 December 2014 with a documented history of increased breathlessness with central chest tightness and productive cough and it was noted she had a history of asthma and COPD and angina. Prior to her admission, Mrs A had been treated at home with nebulised salbutamol, with some improvement.

17. The ambulance Patient Report Form had recorded that Mrs A had a history of penicillin allergy and this information was recorded in the nursing records in the ED. Mrs A was reviewed by a junior doctor who treated her for COPD and heart failure and she was prescribed diuretic treatment before she was referred to the medical team for admission. Mrs A did not receive antibiotics in the ED.

18. Mrs A was then admitted to the ERU around 03:15. Mrs A was reviewed on the morning ward round by a locum consultant physician, who added additional treatment for airways disease and infection. The Board said that, unfortunately, the drug Kardex indicated that Mrs A was prescribed Amoxicillin and Clarithromycin although she was reported as being allergic to penicillin drugs.

19. Later that morning Mrs A was transferred to Ward 17. Mrs A was administered a single dose of 1 gram of Amoxicillin orally around 12:00 on 26 December 2014, as prescribed on the drug Kardex. The Board said that the staff nurse who received the handover from ERU confirmed that there were no allergies passed over during the handover or documented in the nursing notes. However, a record of Mrs A's allergy to penicillin was later found to be documented in her ED record, with a note on the front of the ED card stating 'Red ERU'. The Board said this would indicate that Mrs A had a red allergy identification wrist band applied before her admission to the ERU.

20. However, they were unable to ascertain whether Mrs A was wearing a red allergy identification wrist band when she was given the dose of Amoxicillin or whether such a wrist band was applied after Ms B had spoken to the nurse in charge of Ward 17 on the evening of 26 December 2016. The staff nurse (Nurse 1) who had administered the Amoxicillin to Mrs A has said that she was 'unsure' if Mrs A was wearing a red allergy identification wrist band at the time.

21. The Board acknowledged that it had become apparent that the process concerning patients with red allergy identification wrist bands had not been followed correctly.

The Board's response to SPSO

22. The Board said that Mrs A was admitted to the Hospital at 00:02 on 26 December 2014. A working diagnosis was made of acute exacerbation of asthma/COPD. When Mrs A was reviewed the next morning, during the

consultant ward round in the ERU, the decision was made to give additional treatment for airways disease and to treat the presumed infection with antibiotics. This was when Amoxicillin was prescribed in error. Later that morning Mrs A was appropriately transferred to the in-patient respiratory ward, Ward 17.

23. The Board said it would appear that their handover processes were not robust enough to ensure that the information about Mrs A's allergy was passed over. Unfortunately, drug administration processes were not followed, as this would also have avoided the administration of the Amoxicillin.

24. The Board said they had acknowledged that Mrs A was unreasonably prescribed and administered Amoxicillin when she had a known allergy. The Board said they had apologised to Mrs A's family for this error and provided an action plan (the Action Plan), which documented the actions the Board had taken following receipt of Mr C's complaint.

25. The Board said in order to promote widespread learning they had circulated a clinical incident newsletter, which gave an overview of clinical incidents which had happened in the recent past. This was referred to in the Action Plan. In addition, the Board said they were in the process of developing a Scottish Patient Safety Programme Medicines Management work stream (the Patient Safety Programme) to pull together quality improvement work so as to reduce medication errors.

Medical advice

26. Adviser 1 said that Mrs A was a 68-year-old patient with asthma, COPD, and ischaemic heart disease who had presented to the ED in the early hours of 26 December 2014 with breathlessness, chest tightness and ankle swelling. A diagnosis of pulmonary oedema was made in the ED.

27. Following a consultant review later that day, community acquired pneumonia and a possible COPD exacerbation (flare-up) were added to the diagnoses. Adviser 1 said that Mrs A was prescribed diuretics to offload fluid; steroids as an anti-inflammatory; bronchodilators to relieve a wheeze; and two antibiotics, Amoxicillin and Clarithromycin. Adviser 1 said that although the terms 'LRTI' (lower respiratory tract infection) and 'CAP' (community acquired pneumonia) were recorded in Mrs A's medical records, the indication for prescribing the antibiotics was not clearly documented in the medical records.

28. Adviser 1 said that a chest x-ray carried out had not shown any new radiographic shadowing. Therefore, Adviser 1 considered that Mrs A had not met the criteria for a diagnosis of pneumonia. However, Adviser 1 considered that Mrs A did meet the criteria for a diagnosis of sepsis (infection) taking account of her heart rate, her high breathing rate and she had a fever. Based on this, Adviser 1 considered it was reasonable to start Mrs A on antibiotic therapy. However, Adviser 1 said that Mrs A did not require two antibiotics, given that she had not met the criteria for a diagnosis of pneumonia.

29. Adviser 1 told my complaints reviewer there were no specific guidelines for antibiotic therapy in a patient with a lower respiratory tract infection, but standard practice was to use a broad spectrum penicillin such as Amoxicillin or in patients who are allergic to penicillin another class of class of antibiotic such as Clarithromycin.

30. Adviser 1 said that a history of penicillin allergy was clearly documented in Mrs A's medical records by the admitting nurse and doctor. Despite this, Mrs A was prescribed Amoxicillin and one dose was given to her on 26 December 2014 before the error was noted. Adviser 1 said that the prescription chart appeared to have the 'no known allergies' box ticked then crossed out and 'anaphylaxis to Amoxicillin' added at a later date. Adviser 1 told my complaints reviewer that the correct completion of the allergy section of the prescription chart and the use of the appropriate red allergy identification wrist band should have prevented the administration of penicillin to Mrs A, a patient with a history of anaphylaxis to penicillin. Adviser 1 said that both of these omissions represented serious failings in care.

31. Adviser 1 considered the action the Board said they had taken to address what had occurred in Mrs A's case. Adviser 1 said that although these failings had been acknowledged by the Board, they considered they had not been sufficiently addressed in the Action Plan, as there was no specific reference in the Action Plan as to how they intended to address the failings. Adviser 1 noted that the Action Plan had shown that the Board had carried out a staff debrief about what had occurred. However, Adviser 1 was of the view that the debrief alone was insufficient to prevent a similar situation occurring in the future, given the likely relatively high turnover of nursing and medical staff in the Hospital. Adviser 1 also said that, while the Patient Safety Programme to reduce medication errors was a very appropriate piece of work to have undertaken in

this case, the Action Plan would benefit from additional detail on safer prescribing. Adviser 1 also told my complaints reviewer that the Board should provide my office with an update on the work of the Board's Patient Safety Programme.

Nursing Advice

32. My complaints reviewer also asked Adviser 2 to comment. Adviser 2 said that the handover between nursing staff from the ED to the ERU and then to Ward 17 was appropriately carried out. Adviser 2 explained that the handover is usually a verbal handover from one staff member to another referring to the appropriate documents, in this case the ED record which clearly documented Mrs A's allergy to penicillin. Adviser 2 noted that the ED record also had the box completed about known allergies and penicillin was written in capitals.

33. Adviser 2 commented that the nursing staff in the ED Department were unable to recall who would have fitted Mrs A with a red allergy identification wrist band bracelet, given the number of patients seen in the ED. Adviser 2 said they considered this was reasonable, as every single transaction of a patient's care cannot be recorded.

34. Adviser 2 said the evidence was unclear and it could not be substantiated whether or not Mrs A was wearing a red allergy identification wrist band when she was given the dose of Amoxicillin on 26 December 2014. Adviser 2 said that what had occurred in Mrs A's case was a human error where, for whatever reason, drug administration policies were not followed by staff and was a serious incident. Adviser 2 told my complaints reviewer that while it was not possible to always prevent such an incident occurring due to human error, the Board should review their drug administration policies, in particular their current policy for awareness of allergies, in order to try and prevent such an error recurring.

35. Adviser 2 also said the Board should ensure they provide measures for alerting staff to a patient's allergies, such as by recording this in red in the patient's drug Kardex and in their medical records and checking and recording if a patient is wearing a red allergy identification wrist band.

(a) Decision

36. The Board have acknowledged that Mrs A was unreasonably prescribed and administered Amoxicillin when she had a known allergy to penicillin. The

advice I have received from Adviser 1 is that the correct completion of the allergy section of Mrs A's prescription chart and the use of a red allergy identification wrist band should have prevented this and that the failure to do so represented serious failings in care. Adviser 2 has said that while what had occurred in Mrs A's case was a human error, drug administration policies had not been followed by staff and this was a serious incident. I accept that advice.

37. The Board have said that Nurse 1 was 'unsure' whether Mrs A was wearing a red allergy identification wrist band at the time she administered the Amoxicillin to Mrs A. I acknowledge that Mr C and his daughter Ms B, who is a nurse, have both stated that Mrs A was wearing this type of wrist band when they visited her in the hours after she had been administered the Amoxicillin. Also, the ED record clearly documented Mrs A's allergy to penicillin, which the Board said indicated that Mrs A had been fitted with such a wrist band. While I consider it likely that Mrs A was wearing a red allergy identification wrist band when she was given the Amoxicillin, given there is some uncertainty about this, I am unable to reach a definite conclusion, which is unsatisfactory.

38. I consider what occurred in this case to be a matter of concern, given the potentially serious and harmful implications for Mrs A. In view of these failings, I uphold this complaint.

39. The Board have provided my office with a copy of the Action Plan documenting the actions they have taken following receipt of Mr C's complaint. The advice I have received from Adviser 1 is that the staff debrief which was carried out was insufficient alone to prevent a similar situation occurring in the future, in view of the likely relatively high turnover of nursing and medical staff in the Hospital. Also, the Action Plan would benefit from additional detail on safer prescribing.

40. I also note the advice from Adviser 2 concerning the action the Board should take in relation to their drug administration policies in order to try and prevent such an error occurring.

41. The Board said they had apologised to Mrs A's family for this error. However, I am conscious that Mr C and his family feel they have not received an appropriate apology for what occurred, which has added to their distress.

42. I have, therefore, made the following recommendations to the Board.

(a) Recommendations

43. I recommend that the Board:	*Completion date*
(i) apologise for the failings identified in complaint (a) in relation to the prescribing and administration of Amoxicillin when Mrs A had a known allergy to penicillin;	14 March 2017
(ii) ensure the comments of Adviser 1 and Adviser 2 in complaint (a) about the action that requires to be taken to avoid a repetition of what occurred are brought to the attention of relevant staff and to report back on the action taken;	14 April 2017
(iii) carry out a review of the Action Plan and the Board's policies on drug administration in view of the comments of Adviser 1 and Adviser 2 referred to at paragraphs 31, 34 and 35 and to report back on the action taken; and	14 April 2017
(iv) provide my office with an update on the work of the Patient Safety Programme.	14 April 2017

(b) The Board failed to take appropriate steps when this error was reported to them

Concerns raised by Mr C

44. Mr C said that when Ms B read in Mrs A's medical records that she had been given Amoxicillin, she had immediately spoken to a staff nurse on the ward (Nurse 2) and informed her of Mrs A's anaphylactic history with Amoxicillin. Mr C said that he and his family then left the Hospital at the end of the visiting period, having been assured by Nurse 2 that a doctor was coming to see Mrs A.

45. Mr C said he considered there was a failure by nursing and medical staff to take corrective action when informed that Mrs A had wrongly been given Amoxicillin. Mr C said that the error had not been recorded in Mrs A's medical records. Mr C said that all that had occurred was that Mrs A's drug Kardex had been amended with a score through the entry for Amoxicillin in the allergy section and 'Anaphylaxis-Amoxicillin' recorded in highlighter pen.

46. Mr C said that he believed that the failure to document the incorrect administration of Amoxicillin in Mrs A's medical records meant that this error

was not considered as a possible cause of the subsequent deterioration in Mrs A's condition. Instead, Mr C believed medical staff had pursued the single idea that Mrs A had been suffering from an infection when, in fact, none was found.

The Board's response to Mr C

47. The Board said that after the incident had been reported by Ms B, Nurse 2 had contacted the on-call doctor. However this, unfortunately, was not documented in Mrs A's nursing notes. There was also no documentation in Mrs A's medical records to evidence that a doctor examined Mrs A at the time. The Board have since told my office that when this error was brought to light a doctor was called and reviewed Mrs A but they accepted that, unfortunately, this was not documented in Mrs A's medical records.

48. The Board said Amoxicillin was discontinued from Mrs A's Kardex as well as the admission documentation and Mrs A was continued on Clarithromycin alone.

49. The Board said they acknowledged that the response of nursing and medical staff to Mrs A wrongly being administered Amoxicillin had been deficient. There was no evidence in the medical records of heightened observations and, on reflection, the Board accepted there should have been a period of increased observation of Mrs A in order to monitor any potential adverse reaction. The Board also accepted that the incident was not reported at the time on the Board's Datix incident report system. This, the Board said, fell below the expected standard of care.

50. The Board said that despite the single dose of 1 gram of Amoxicillin being administered early in the course of Mrs A's admission, Mrs A's clinical state including her heart rate and blood pressure suggested she suffered no adverse consequences.

51. The Board said that Nurse 1, who administered the Amoxicillin, had apologised to Mrs A and her family for the error. The Board had also apologised to Mrs A's family that the error had occurred.

The Board's response to SPSO

52. The Board told my office that the process failures identified in Mrs A's case had formed a large part of the Board's learning and actions from the complaint.

Medical advice

53. Adviser 1 told my complaints reviewer that Mrs A's deterioration in her symptoms occurred 24 hours after the administration of the Amoxicillin and there were no reported skin changes. Therefore, Adviser 1 said that the diagnostic criteria for a diagnosis of an anaphylactic reaction to the Amoxicillin were not met. In addition, Adviser 1 noted that subsequent blood tests which were carried out for anaphylaxis were negative. Based on these two facts, Adviser 2 said that Mrs A's deterioration was not due to the administration of Amoxicillin.

54. Adviser 1 said, however, there was no documentation in Mrs A's medical records regarding the action taken after Mrs A was given the Amoxicillin. Adviser 1 commented that the Board's response to the complaint had confirmed there was no evidence that a doctor was called to assess Mrs A and the frequency of observations had not been increased. Adviser 1 told my complaints reviewer that, given that it had been reported to staff that Mrs A had a history of anaphylaxis to penicillin, it should have been standard practice to increase the frequency of observations and to seek an urgent medical review of Mrs A. Adviser 1 said the event should have been documented within Mrs A's medical records. Adviser 1 told my complaints reviewer the fact that none of these actions occurred represented serious failings in Mrs A's care.

55. Adviser 1 said that although these failings had been acknowledged by the Board, they considered they had not been sufficiently addressed in the Action Plan, as there was no specific reference in the Action Plan as to how they intended to address the failings. Adviser 1 said the Action Plan would benefit from additional detail on the assessment of patients who had undergone an adverse event.

Nursing advice

56. Adviser 2 said if an anaphylactic reaction was expected, this would be likely to occur immediately. Adviser 2 considered that one of the key mistakes that had occurred was that Nurse 2 did not report the incident immediately as an error and had not completed this on the Hospital's Datix incident reporting system. There were also no entries in the medical records about who or when staff were aware of the drug error. Adviser 2 told my complaints reviewer there must have been recognition of the error when the Amoxicillin was discontinued, however, they could find no record of this in the medical records. Adviser 2 said

nursing staff did not carry out more frequent observations, which was likely due to the fact they were unaware of the incident as it had not been recorded in Mrs A's medical records.

57. Adviser 2 noted that the Board had acknowledged that errors had been made and had met with Mrs A's family to discuss their concerns. Adviser 2 also told my complaints reviewer that it was important that staff should feel supported to report errors, which in turn should encourage improvement, and it was important that the staff involved and the Board more generally learned from this error. Adviser 2 said the Board should provide evidence to show how they share learning and encourage staff to report early when errors have occurred.

(b) Decision

58. The advice I have received from Adviser 1, which I accept, is that Mrs A's deterioration was not due to the administration of Amoxicillin on 26 December 2014.

59. When responding to the concerns raised by Mr C, the Board have accepted there were failures in the response of nursing and medical staff to Mrs A wrongly being administered Amoxicillin: in particular, in not carrying out increased observations of Mrs A in order to monitor any potential adverse reaction; in record-keeping; and not reporting the incident at the time on the Board's Datix incident report system. The Board have acknowledged these failings fell below an expected standard of care that Mrs A should have received. Adviser 1 has said the failure to carry out these actions represented serious failings in Mrs A's care.

60. I am satisfied there was a failure by both nursing and medical staff to take appropriate action after Mrs A was wrongly administered Amoxicillin. Therefore, I uphold the complaint.

61. While these failings have been acknowledged by the Board, the advice I have received from Adviser 1 is that the Action Plan does not sufficiently address how the Board intend to address them: in particular, in relation to the assessment of patients who have undergone an adverse event.

62. In addition, I agree with Adviser 2 the importance of the Board's staff feeling supported to report errors when they occur, so that they and the Board more generally learn from such errors in order to try and prevent the errors

happening again. Therefore, I have asked the Board to provide my office with evidence of how they encourage staff to report early when errors have occurred and how they ensure learning is shared with their staff.

63. The Board have said that they and Nurse 1 had apologised to Mrs A's family. I also acknowledge that the Board met with the family. However, as I have stated in complaint (a) above, Mr C and his family feel they have not received an appropriate apology for what occurred and which had added to the family's distress at a very difficult time.

(b) Recommendations

64. I recommend that the Board:	*Completion date*
(i) apologise for the failings identified in complaint (b) in relation to the failure to take appropriate action when it was reported that Mrs A had wrongly being administered Amoxicillin;	14 March 2017
(ii) ensure the comments of Adviser 1 and Adviser 2 in complaint (b) are brought to the attention of relevant staff and to report back on the action taken;	14 April 2017
(iii) carry out a review of the Action Plan in view of the comments of Adviser 1 referred to at paragraph 55 and to report back on the action taken; and	14 April 2017
(iv) provide evidence to show how they encourage staff to report early when errors occur and how they share the learning from such errors with staff.	14 April 2017

(c) The Board failed to provide a reasonable standard of treatment

Concerns raised by Mr C

65. Mr C said he and members of his family visited Mrs A on the afternoon of 27 December 2014. He said Mrs A told him that earlier in the day she had suffered a fit and the Hospital Emergency Care Team (HECT) had been called to review her. Mr C said that, during the visit, when Mrs A had gone to the bathroom she was visibly extremely breathless; she had an audible wheeze; she could hardly speak; and was complaining of dizziness.

66. Mr C said that Ms B had spoken to a nurse to voice the family's concerns about Mrs A and had been informed that the HECT had examined Mrs A and concluded that she had got a fright and they had no concerns about Mrs A.

Mr C said during the visit Mrs A's oxygen levels had fluctuated and incorrect readings were recorded in Mrs A's medical records. A junior doctor had subsequently reviewed Mrs A, who had concluded that she was suffering from anxiety and a salbutamol tremor. However, Mr C said he and his family felt the family's concerns had been dismissed. In addition, Mr C said they were also concerned that Mrs A had not been seen by a consultant physician.

67. Mr C said that he and members of his family visited Mrs A on the evening of 27 December 2014. Mrs A had appeared to further deteriorate; she was extremely breathless with an audible wheeze and finding it difficult to talk. Mr C said that Mrs A was also confused.

68. Mr C said he received a telephone call from a nurse in Mrs A's ward on the morning of 28 December 2014 to inform him that Mrs A had been unwell during the night. Mr C said he later learned that a doctor had been called to examine Mrs A.

69. On morning of 28 December 2014, following a request from Mrs A to visit, Mr C said he and his family arrived to find that Mrs A had been moved to a side room in Ward 17. Mr C said Mrs A was struggling to breathe, she was on oxygen and only capable of saying single words. Also, her conscious level had decreased. Mr C said that on making enquiries with the nursing staff about the deterioration in Mrs C's condition he was informed that a doctor had been called, but had not yet arrived to examine Mrs A. Mr C said he was also told a doctor had examined Mrs A during the night and they suspected she had a pulmonary embolism.

70. Mr C said that a doctor had examined Mrs A later that afternoon, after Mrs A had a computerised tomography (CT) scan, and was of the view that Mrs A had an infection. Mr C said that Ms B asked for Mrs A's blood gasses to be checked and about her suitability for transfer to the ICU, but was told this was not appropriate. However, Mr C said that it was later confirmed that Mrs A's blood gasses showed that she is was in respiratory failure and bi-level positive airway pressure (Bipap) treatment was started.

71. Mr C said that on 29 December 2014 Mrs A was reviewed by a consultant physician (the Consultant) who informed them that he would refer Mrs A's case to the ICU and arrange for an anaesthetist to review Mrs A, which was carried out later that day. A decision was made to transfer Mrs A to the ICU in early

evening. Mrs C said they were then informed by a member of the nursing staff that Mrs A's transfer to the ICU would be delayed, due to an emergency concerning another patient. Mrs A was transferred that evening to the ICU.

72. Mr C said that Mrs A's condition continued to deteriorate and she died on 2 January 2015.

73. Mr C said he and his family considered there were many unanswered questions about Mrs A's treatment and why her condition had deteriorated, leading to her death. Mr C said he and his family questioned the reasonableness of the treatment Mrs A had received.

The Board's response to Mr C

74. The Board said that on the morning of 27 December 2014 it was noted that Mrs A had an episode lasting approximately four seconds where she appeared vague and her limbs had 'jerked'. The HECT were on the ward at the time and were asked to review Mrs A. They concluded that Mrs A was fully conscious and was tired and there was no evidence to suggest a seizure. Therefore, there was no change in Mrs A's management plan at the time.

75. Mrs A was again examined by a doctor on the afternoon of 27 December 2014 following concerns raised by Ms B that Mrs A was feeling unwell and dizzy. Mrs A was found to be alert and orientated and her bloods were checked and found to be unremarkable. A doctor who examined Mrs A considered her dizziness was due to increased nebulisers and an element of anxiety. It was planned to review her the next day and to continue with regular observations.

76. Mrs A seemed reasonably stable until 22:30 on 27 December 2014 when she appeared to have an increase in her respiratory rate, increased heart rate, increased temperature and slightly reduced oxygen saturation. The on-call doctor was called and Mrs A was considered to have sepsis. Intravenous Levofloxacin was added to Mrs A's antibiotic treatment, antihypertensive drugs were withheld and an intravenous fluid challenge was given. A variety of cultures were also obtained for microbiology testing. Mrs A was seen at that stage by a senior member of the medical staff.

77. Mrs A was next seen on 28 December 2014 at 04:10, after nursing staff contacted the HECT at 03:40. This was due to Mrs A becoming more short of

breath and complaining of chest pain. Mrs A deteriorated further and it was felt that the possibility of pulmonary thromboembolism should be considered. Treatment was started for this condition using Tinzaparin, an anticoagulant medication that helps prevent the formation blood clots, and a CT pulmonary angiogram was to be arranged later that day and hourly observations commenced. Two hours later, at 06:00, the arterial blood gas measurement indicated that Mrs A's arterial carbon dioxide, which was normal at the time of her admission, had begun to rise along with evidence of a respiratory acidosis. She was given further bronchodilator treatment and seemed more settled. There was intensive monitoring of Mrs A thereafter, with records made at least every hour with several further reviews by a senior doctor.

78. By the afternoon of 28 December 2014, although the CT pulmonary angiogram did not show that Mrs A had a pulmonary embolism, she had deteriorated again with a high respiratory rate, high heart rate, rising arterial carbon dioxide and worsening respiratory acidosis. She was started on non-invasive ventilator support at 15:50 that day. There was evidence of a slight initial improvement in her condition, which was not sustained, and on the morning of 29 December 2014 she had a worsening arterial carbon dioxide once again.

79. Mrs A was seen by the Consultant for the first time on 29 December at 12:40. The Board said that the clinical picture at that time suggested that Mrs A had an infective exacerbation of her airways disease, resulting in worsening ventilatory failure. Non-invasive ventilatory support was inadequate and it was decided to transfer Mrs A to the ICU for consideration of invasive ventilation, with the plan to keep her on non-invasive ventilatory support meantime but in the ICU. Unfortunately, there was a delay in transferring Mrs A to the ICU, due to another patient requiring the involvement of all members of the ICU and anaesthetic team. On reflection, the Board said they did not believe the delay in transferring Mrs A was unreasonable or had been detrimental to Mrs A or that it had had any effect on the eventual outcome for Mrs A.

80. The Board said that whilst in the ICU Mrs A deteriorated progressively with worsening ventilatory failure and her condition did not improve with the treatments given.

81. According to the Board, there was no evidence in Mrs A's medical records which suggested that Mrs A had developed an adverse reaction to the single dose of Amoxicillin or that it had had an adverse effect on her circulation.

The Board's response to SPSO

82. The Board told us that on 27 December 2014 a deterioration in Mrs A's condition was noted and, on review by a middle grade medical doctor, she was considered to have sepsis and was started on Levofloxacin. Samples were taken for laboratory analysis and microbiology. That night Mrs A was seen by the same doctor and by the HECT nurses. A diagnosis of pulmonary thromboembolism was considered and treatment was started with a CT pulmonary angiogram arranged later that day, which did not show a pulmonary embolism.

83. By the afternoon of 28 December 2014 Mrs A had deteriorated again and a blood sample taken from her artery, which indicated type 2 respiratory failure (low oxygen, high Co2) and it was at this point she was commenced on Bipap treatment.

84. The Board said there was some clinical evidence of an improvement in Mrs A's condition, which was not sustained, and on the morning of 29 December 2014 she was reviewed by the Consultant who referred Mrs A to the ICU. Mrs A was accepted for the ICU but it was not considered at the time necessary to escalate her treatment to invasive ventilation. Unfortunately, a critically urgent situation developed with another patient in the ICU and this resulted in a delay in transferring Mrs A to the ICU. Thereafter, Mrs A deteriorated that evening and required invasive ventilation and organ support. Sadly, Mrs A died on 2 January 2015.

85. The Board said that a respiratory tract virus had been detected on testing and Mrs A's condition was considered to be sepsis, secondary to lower respiratory tract infection. Consideration had been given as to whether Mrs A had ever suffered an anaphylactic type reaction. While Amoxicillin should not have been prescribed or administered to Mrs A, none of the clinicians involved in Mrs A's care believed this to be the case and there was no suggestion that an anaphylactoid response was seen or responsible for Mrs A's subsequent clinical course.

Medical advice

86. Adviser 1 noted that Mrs A had a brief unresponsive episode, having been breathless following mobilisation to the toilet on the morning of 27 December 2014. Adviser 1 said that Mrs A was promptly assessed by the HECT, then by a junior doctor.

87. Adviser 1 told my complaints reviewer that, given Mrs A's history of asthma and the continued presence of a wheeze in both her lungs at this time, a diagnosis of acute severe asthma should have been considered. Adviser 1 referred my complaints reviewer to the British Guideline on the Management of Asthma (the Guidance on the Management of Asthma) which Adviser 1 said recommended peak expiratory flow measurement as part of the assessment of the severity of acute asthma. The Guidance on the Management of Asthma also recommended an arterial blood gas measurement if there were any signs of life threatening asthma. Given the nature of the episode, together with Mrs A having an oxygen saturation of 92 percent and low diastolic blood pressure, Adviser 1 said that an arterial blood gas measurement should have been performed. Adviser 1 explained to my complaints reviewer that not performing a peak flow or arterial blood gas measurement represented a failure to adhere to the Guidance on the Management of Asthma. Adviser 1 also explained that the results may have highlighted the need for escalation in the management of Mrs A's airways disease which could have changed the subsequent outcome.

88. Adviser 1 noted that, later on 27 December 2014, Mrs A's condition deteriorated and a diagnosis of sepsis was made and her antibiotic therapy was escalated. However, despite this there was further deterioration in Mrs A's condition.

89. Adviser 1 said that in the early hours of 28 December 2014 Mrs A became more breathless, with a further drop in oxygen saturations and a widespread wheeze was again noted. The arterial blood gas measurement showed lung failure with low oxygen and high carbon dioxide levels. Adviser 1 said that Mrs A's condition at this time was in keeping with either a life threatening asthma attack or, if COPD was the primary problem, a life threatening COPD exacerbation. Adviser 1 said review by the intensive care team for ventilatory support was recommended by the Guidance on the Management of Asthma if the carbon dioxide level was raised and by the 2008 British Guideline on non-invasive ventilation in COPD (Guidance on non-invasive ventilation in COPD) if the pH (blood acid level) was less than 7.25. Adviser 1 said that Mrs A met

these criteria. In the view of Adviser 1, not making a referral to the intensive care team at this point represented a failure to adhere to national guidelines. In addition, Adviser 1 was of the view that earlier use of ventilatory support may have prevented Mrs A's further deterioration by reducing the level of carbon dioxide associated acids in the blood, which would have allowed for better respiratory muscle function and ventilation. This, in Adviser 1's view, may have altered the outcome.

90. Adviser 1 told my complaints reviewer that as the standard of assessment when Mrs A's condition first deteriorated on the morning of 27 December 2014 and the subsequent treatment in the early hours of 28 December 2014 in not adhering to national guidelines was a serious failing and had not been acknowledged by the Board in their response to the complaint from Mrs A's family.

91. Adviser 1 said that, on the afternoon of 28 December 2014, Mrs A's arterial blood gas measurement had deteriorated further and she was started on non-invasive ventilation (NIV) on the ward. Given the uncertainty over the primary diagnosis (asthma versus COPD) and the deterioration in Mrs A's blood acid levels, Adviser 1 considered that Mrs A should have been referred for ventilator support to the ICU at this point which Adviser 1 said was in keeping with the Guidance on non-invasive ventilation in COPD.

92. Adviser 1 said it was not clear at what time the decision was made to transfer Mrs A to the ICU, as the entry in the medical records from the ICU consultant had the incorrect date and was not timed. Adviser 1 said there were no further medical entries in the medical records until Mrs A was moved to the ICU at 19:30 on 29 December 2014. Adviser 1 told my complaints reviewer that once the decision was made to move Mrs A from Ward 17 to the ICU, although there appeared to be a three hour delay, they did not consider that this delay had affected the outcome for Mrs A.

93. Adviser 1 said that following Mrs A's transfer to the ICU she developed shock (low blood pressure) and worsening bronchospasm (airway narrowing) which did not respond to treatment. Sadly, Mrs A died on 2 January 2015. Adviser 1 considered that the treatment Mrs A received in the ICU from 29 December 2014 to 2 January 2015 had been appropriate.

94. Adviser 1 said that Mrs A had presented with an infective exacerbation of airways disease, either asthma, COPD or both. Adviser 1 considered Mrs A's deterioration to have been due to worsening of the underlying condition. Adviser 1 told my complaints reviewer they were satisfied that Mrs A's deterioration had not been due to the administration of Amoxicillin. However, Adviser 1 said they considered there were opportunities to identify the severity of the deterioration in Mrs A's condition on day two of her admission, as opposed to day three of her admission, which should have prompted an earlier review and additional treatment by the ICU medical team. This may have altered the outcome for Mrs A.

95. Adviser 1 said that the Board in the Action Plan had focused on whether the administration of Amoxycilin had contributed to Mrs A's deterioration, which it had not. Adviser 1 also told my complaints reviewer that the Action Plan referred to an update of the NIV protocol but did not state how the Board would address the specific issue of early recognition and treatment of significant respiratory failure, particularly when there was uncertainty over the underlying diagnosis. Adviser 1 said that the Board should provide clarification of the changes made to the NIV protocol. Adviser 1 also considered the Action Plan would benefit from additional detail on earlier recognition of critically ill patients.

96. Adviser 1 noted that the majority of the Action Plan was implemented eight to nine months after what had happened to Mrs A. The Board had said this was due to the absence of a member of staff but Adviser 1 said he would expect an alternative member of staff to have been identified to oversee the Action Plan.

97. Adviser 1 also told my complaints reviewer that the Board should have carried out a significant adverse event (SAE) review in this case. While Mrs A's case had been discussed at the ICU Morbidity and Mortality meeting, which Adviser 1 said was good practice, the failings in care occurred prior to Mrs A's transfer to the ICU. Therefore, Adviser 1 would also have expected Mrs A's case to have been discussed at a respiratory or general medicine morbidity and mortality meeting. (When commenting on a draft of this report, the Board advised my office that a Medical Directorate Morbidity and Mortality Meeting to discuss Mrs A's case was held on 24 February 2016.)

98. Overall, Adviser 1 considered the Board had not fully acknowledged the seriousness of what happened in Mrs A's case, had not identified all the relevant learning and not taken all necessary action to avoid a recurrence.

Nursing Advice

99. Adviser 2 also told my complaints reviewer that a SAE review should have been instigated, as this type of review is intended to explore the reasons mistakes are made and to reduce the probability of them happening again.

(c) Decision

100. The advice I have received from Adviser 1, which I accept, is that the deterioration in Mrs A's deterioration was due to the worsening of an underlying condition and was not due to the administration of Amoxicillin on 26 December 2014.

101. However, it is of significant concern that there was an unreasonable delay in assessing and treating the deterioration in Mrs A's condition. As Adviser 1 has identified, there were missed opportunities to consider a diagnosis of acute severe asthma in Mrs A; to adhere to national guidelines; and to identify the severity of the deterioration in Mrs A's condition earlier on in her admission. Also, Mrs A should also have been referred earlier to the intensive care team. All of which represented a serious failure in Mrs A's care. I am critical that the failings identified have not been acknowledged by the Board in their response to the complaint from Mrs A's family. I also appreciate that it will be very distressing for Mrs A's family to learn that the failings identified may have altered the outcome for Mrs A.

102. For these reasons, I uphold the complaint.

103. Both Adviser 1 and Adviser 2 have told me that, given the seriousness of the failings which occurred before Mrs A was transferred to the ICU, an SAE review should have been carried out by the Board. While I acknowledge the action the Board have taken, I also note that the Action Plan lacks detail in relation to addressing the specific issue of early recognition and treatment of significant respiratory failure in a patient, particularly when there is uncertainty over their underlying diagnosis, and also earlier recognition of critically ill patients.

104. To address this, I have made the following recommendations.

(c) Recommendations

105. I recommend that the Board:	*Completion date*
(i) apologise for the failings in Mrs A's treatment identified in complaint (c);	14 March 2017
(ii) ensure the comments of Adviser 1 and Adviser 2 in complaint (c) are brought to the attention of relevant staff and to report back on the action taken; and	14 April 2017
(iii) carry out a review of the Action Plan in view of the comments of Adviser 1 referred to at paragraphs 95; 96 and 97 and to report back on the action taken.	14 April 2017

106. 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 dates 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
Mrs A	the complainant's wife
the Hospital	Monklands Hospital
COPD	Chronic Obstructive Pulmonary Disease
ED	Emergency Department
ERU	Emergency Receiving Unit
Ms B	the complainant’s daughter
ICU	Intensive Care Unit
the Board	Lanarkshire NHS Board
Adviser 1	consultant in respiratory medicine
Adviser 2	nursing adviser
Nurse 1	a nurse on Ward 17
the Action Plan	the Board's Action plan
the Patient Safety Programme	Scottish Patient Safety Programme Medicines Management work stream
Nurse 2	a nurse on Ward 17
HECT	Hospital Emergency Care Team
CT	computerised tomography

Bipap	bi-level positive airways pressure
the Consultant	a Consultant physician
the Guidance on the Management of Asthma	British Guideline on the Management of Asthma
Guidance on non-invasive ventilation in COPD	British Guideline on non-invasive ventilation in COPD (2008)
NIV	non-invasive ventilation
SAE	significant adverse event

Annex 2

Glossary of terms

Amoxicillin	a penicillin antibiotic
anaphylaxis	a severe allergic response
angina	chest pain caused by the blood flow to the muscles being restricted
bi-level positive airway pressure treatment (Bipap)	a method of breathing support
bronchodilator	a drug that widens the air passages of the lungs
chronic obstructive pulmonary disease (COPD)	a lung disease
Clarithromycin	an antibiotic used to treat various bacterial infections
CT pulmonary angiogram	a procedure to obtain an image of the pulmonary arteries
invasive ventilation	anaesthetising and inserting a tube into the windpipe
Levofloxacin	a non-penicillin antibiotic
non-invasive ventilation (NIV)	supported breathing via a ventilator and face mask
Prednisolone	a steroid medicine
pulmonary embolism	a blockage in the artery to the lungs

pulmonary thromboembolism	a blood clot that travels through the bloodstream and causes a blockage of an artery in the lungs
refractory cardiovascular collapse	failure of the circulatory system
respiratory acidosis	a condition that occurs when the lungs cannot remove enough of the carbon dioxide produced by the body
salbutamol	medication used to treat an asthma attack

Annex 3

List of legislation and policies considered

British Guideline on the Management of Asthma

British Guideline on non-invasive ventilation in COPD (2008)