Case 200402133: Lothian NHS Board

Case 200501127: Argyll & Clyde NHS Board[4]

Case 200501128: A General Practitioner in the Argyll and Clyde NHS Board area

Introduction

1. In February 2005 the Ombudsman received a complaint from a man (referred to in this report as Mr C) about the inadequate care and treatment of his daughter (referred to in this report as Miss A) from several NHS services in Scotland between 20 January 2003 and 22 January 2003. Mr C complained that the combined failure to diagnose and treat Miss A's deep vein thrombosis (DVT) directly contributed to Miss A's death from a pulmonary embolism on 26 January 2003. Mr C was supported in his complaint by Mrs C (Miss A's mother) and Miss A's brother.

2. During the relevant period Miss A was seen as an out-patient at the Royal Infirmary of Edinburgh (the RIE), the Royal Alexandra Hospital (the RAH), Paisley and in the practice surgery by her family General Practitioner (the GP). These events are all related and relevant to Mr C's complaint and have been investigated as one complaint.

3. The complaints from Mr C which I have investigated *(and my conclusions)* are that:

(a) the RIE failed to properly and adequately assess Miss A's condition on 20 January 2003 *(partially upheld – paragraphs 22 to 26)*;

[4] Argyll and Clyde Health Board (the former Board) was constituted under the National Health Service (Constitution of Health Boards) (Scotland) Order 1974. The former Board was dissolved under the National Health Service (Constitution of Health Boards) (Scotland) Amendment Order 2006 which came into force on 1 April 2006. On the same date the National Health Service (Variation of the Areas of Greater Glasgow and Highland Health Boards) (Scotland) Order 2006 added the area of Argyll and Bute Council to the area for which Highland Health Board is constituted and all other areas covered by the former Board to the area for which Greater Glasgow Health Board is constituted. The same Order made provision for the transfer of the liabilities of the former Board to Greater Glasgow Health Board (now known as Greater Glasgow and Clyde Health Board) and Highland Health Board. In this report, according to context, the term 'the Board' is used to refer to the former Board or Greater Glasgow and Clyde Health Board as its successor. However, the recommendations within this report are directed towards Greater Glasgow and Clyde Health Board.

(b) GP 1 failed to refer Miss A to an appropriate Acute Care facility on 22 January 2003 *(not upheld – paragraph 30)*;

(c) the RAH failed to properly and adequately re-assess Miss A's condition on 22 January 2003 *(upheld – paragraphs 35 to 36)*.

4. As the investigation progressed a further concern arose about the apparent lack of an integrated care pathway for those patients in Scotland who present at facilities operated by more than one NHS Board. I address this issue in paragraph 36 to 39. The Ombudsman identified an issue of concern for the NHS throughout Scotland and will notify this concern to the Scottish Executive Health Department and NHS Quality Improvement Scotland (the organisation within NHS Scotland responsible for producing national standards and guidelines).

5. Specific recommendations the Ombudsman is making resulting from this investigation are that:

i. the RIE review what information – both written and oral – is currently made available to patients who have been reviewed for possible DVT. The Board should consider revising the DVT Management Protocol to include specific guidance on oral information to be given to patients about continued or progressing symptoms and consider the use of a Patient Information Leaflet for discharged patients;

ii. the RIE discuss the events of this case at an appropriate multi-disciplinary team meeting to highlight the limits of the available tests and the need for technical accuracy in communication;

iii. the RAH audit cases of suspected DVT presenting at Accident and Emergency to ensure that there is compliance with the use of the DVT Clinical Assessment Form;

iv. the RAH discuss the events of this case at an appropriate multi-disciplinary team meeting to highlight the limits of the available tests, the need for technical accuracy in communication and what processes should be adopted when reaching a second opinion.

Investigation and findings of fact

6. Investigation of this complaint involved a meeting with Mr and Mrs C (Miss A's parents), reviewing Miss A's relevant GP records and hospital records, obtaining the opinion of a medical adviser (referred to in this report as the adviser), reading the documentation provided by Mr C (including a recording of a meeting with NHS Lothian and the post mortem report) and making written enquiries of both NHS Boards and the GP. Mr C, Lothian NHS Board, Argyll and Clyde NHS Board and the GP have all had an opportunity to comment on the draft report. An explanation of abbreviations used is contained in Annex 1. A glossary of medical terms is contained in Annex 2.

Medical Background

7. A deep vein thrombosis (DVT) is a blood clot (thrombus) that develops in a deep vein, usually in the leg. This can happen if the vein is damaged or if the flow of blood slows down or stops. About one in 2,000 people in the UK develops a DVT each year. If the clot breaks away and travels up the vein to block a blood vessel in the lung, this is called a pulmonary embolism and can be life threatening. The most common symptoms of a DVT in the leg are swelling and pain in the affected leg. These symptoms are caused by the accumulation of blood that is unable to get past the clot in the vein and the resulting leakage of fluid from the blood into the muscle. Many other conditions exhibit symptoms similar to those of a DVT, for example, muscle strains and inflammation of superficial veins. A DVT is often very difficult to diagnose. A number of screening and diagnostic tests can be used in the diagnosis of DVT.

8. A common screening tool used is known as the Wells Test. This test uses a scoring system for symptoms and, based on the predictive value of these symptoms, assess a probability of DVT. The test results are used to evaluate whether and to what degree further tests should be performed.

9. Among a number of other screening tests used (often following a Wells Test assessment) is impedance plethysmography. In this procedure, blood pressure cuffs are placed on the legs to determine the pressures at which the veins are filled or emptied, so that obstructing blood clots can be identified. This test had a false positive rate of 25% (indicates a DVT may be present where in fact there is none) and can only be used to screen out; that is, where a test is normal, DVT is unlikely. An abnormal test indicates further testing is needed before a DVT can be excluded not that there is definitely a DVT. There is no accurate blood test for detecting a DVT. The only available blood-test

(known as D-dimmer) is again only of use in eliminating a diagnosis of DVT and is used as a screening tool before progressing to a diagnostic test. It is of no greater predictive value than plethysmography and these two tests are used alternately rather than in combination.

10. Venography is a diagnostic test. This test is performed by injecting a dye that can be seen on an x-ray into a vein on the top of the foot. The dye flows with the blood and fills the veins of the leg, thigh, and pelvis. An obstructing blood clot in one of these veins can be seen on an x-ray as a dye-free area within the vein. Venography is the most accurate test available to identify a DVT and is often referred to as 'the gold standard'. Venography requires a high degree of expertise to perform and interpret correctly. Venograms themselves carry a 4% risk of causing a DVT and are regarded as being a very invasive test. For these reasons (and others) the venogram has been slowly replaced by duplex ultrasonography (uses sound waves to produce images of veins and arteries) as the test of choice in most hospitals in the UK. This allows doctors to assess a patient without x-rays or puncturing arteries and veins. It is not, however, as accurate as venography and still requires skilled interpretation by a radiologist.

Medical History

11. On 20 January 2003 Miss A presented at the accident and emergency department of the RIE, complaining of a painful lower left leg which became worse when she walked. Mrs C was with Miss A for much of this admission. The medical record noted Miss A had experienced pain since 17 January 2003 but had not suffered any injury to her leg. Other known risk factors were assessed and it was noted that Miss A suffered from Polycystic Ovary Disease and took contraceptive pills to address the pain caused by this condition. It was noted that her left calf was 1cm larger than the right (anything less than a 3 cm difference is not regarded as clinically significant). She was assessed by the Sister and noted to have a positive plethysmography test. Because of this positive test result a venogram was ordered. The venogram test result was noted by a specialist registrar as 'No thrombosis seen on this examination therefore low probability of DVT'. Miss A was discharged with advice to attend her GP within eight days and to use an elastic bandage. She was given advice on pain relief and told to see her GP if the pain increased. The records do not indicate any advice being given to return if other symptoms continued or developed. The principal diagnosis noted on the discharge summary was 'Exclusion of DVT'. Miss A returned to her family home, outwith Lothian NHS

Board area, early the next day.

12. The following day, 21 January 2003, Miss A attended her family GP (the GP) as she was experiencing increased pain in her leg. The GP noted that the venogram had been negative and that her left calf was tender to touch. The GP noted that there was no redness and no significant swelling in the left calf. He diagnosed a muscle injury and prescribed stronger painkillers. A further prescription of volterol was added later that day following a request from Mrs C.

13. On 22 January 2003 Miss A's pain had not improved and Mrs C called the GP to discuss what should be done next. The GP advised her to take Miss A to the accident and emergency department at the RAH for further review. Miss A, accompanied by Mrs C, attended the RAH. Her initial examination noted her risk factors as before with regard to taking a contraceptive pill (see paragraph 11). Her symptoms were noted as tenderness of the left calf and no increase in the swelling of the left leg from that found at the RIE (a 1 cm difference only). The doctor at the RAH called the GP and discussed the results of the RIE investigations. The record notes that the letter from the RIE states 'exclusion of DVT'. Miss A was discharged with advice to continue with all pain relief and return if she experienced an increase in swelling, skin redness, shortness of breath or chest pain.

14. Mrs C provided a written statement (made on 14 March 2003) which described her involvement in events and a description of Miss A's condition on the 23 to 25 January 2003. Mrs C noted that Miss A had specifically discussed the possibility of DVT with the doctors at the RIE and the RAH. She noted that both she and Miss A had professional experience of the symptoms of DVT and understood the condition. Mrs C stated that the doctor at the RAH repeated the diagnosis of a muscular injury although Miss A specifically stated that she had not injured a muscle and it was not muscular pain. Mrs C described Miss A's pain as lessening on the 23 and 24 January 2003 although the calf muscle became very stiff and Miss A could not walk. Mrs C recorded that she suggested to Miss A that she represent at the GP surgery but Miss A was reluctant to do so as she felt she was not being listened to.

15. On 26 January 2003 Miss A became unwell at 04.30 and Mr C called an ambulance which took Miss A to the Inverclyde Royal Hospital in Greenock. Miss A's condition deteriorated rapidly in the ambulance and despite resuscitation efforts at the hospital she sadly died. Post mortem noted the

cause of death to be pulmonary thrombo-embolism due to leg vein thrombosis.

16. The post-mortem report concluded that the blood clot in the leg had probably been present for several days.

(a) The Royal Infirmary of Edinburgh failed to properly and adequately assess Miss A's condition on 20 January 2003.

17. At a meeting between Mr and Mrs C and NHS Lothian to discuss the issues of this complaint, the Board stated that if a patient's test for DVT was negative but they continue to have symptoms then it was normal practice to reinvestigate when a patient re-presented.

18. The Board told Mr C that when staff at the RIE learned of Miss A's death they undertook a complete critical incident review of her care and of the test results. This review concluded that all staff involved had acted appropriately and with the necessary skill. The venogram was appropriately reviewed by a consultant at the time it was performed and had subsequently been reviewed by another Consultant Radiologist who confirmed the original findings.

19. The adviser commented that the clinical notes were of a high standard and were clearly recorded on a care pathway that allowed appropriate investigation and management of possible DVT, commencing with the Wells Test. He noted that the venogram was reported by a radiology registrar and reviewed by a consultant at that time. This was consistent with good practice. I have seen no evidence to suggest that the venogram was misinterpreted or that there was any error in the procedure. The adviser stated that venography is the most sensitive and accurate investigation for DVT but can never be 100% accurate. The adviser said that in Miss A's case the venogram was accurately reported by recording that there was a low probability of DVT. The adviser commented that this was subsequently interpreted by Miss A's medical team as 'excluding' DVT which it could never do. I note that this was the information transmitted to Miss A's GP and the medical team in the RAH. I also note that there is a considerable body of medical literature which refers to the venogram as the 'gold standard' test without mention of the very small number of instances where it will not detect a DVT. These failures are due to a number of circumstances which while minimal can be catastrophic as in Miss A's case.

20. Mr C questioned the accuracy of the Wells Test result for Miss A at the RIE. This test gave a very low probability of DVT because the score was adjusted

downwards as the list of symptoms included a check mark against ‘another diagnosis more probable than DVT’. The adviser commented that there was no evidence to support any alternative diagnosis and considered that the Wells Test was probably not used accurately in this instance. However, he noted that the Wells Test is only used to assess the need for further testing and that in this case that further testing did occur despite the low probability score. He considers this discrepancy did not directly influence the treatment of Miss A.

21. In response to the draft report Lothian NHS Board have commented that the reality of the situation is that there was no evidence of a significant DVT. They have told me that there is a relatively limited range of alternative diagnosis for DVT and in the absence of another obvious cause musculoskeletal injury is often considered. The Board also advised me that the incidents of this case have been discussed at a critical incident meeting and further review groups. The Board also has a multi-disciplinary group in place reviewing management of this condition. A patient leaflet has been introduced since the time of these events. I have had sight of this leaflet and consider it is a very useful addition to patient information. However, I note the leaflet includes specific reference to the 'exclusion' of DVT which suggests a greater degree of certainty than is currently medically possible.

(a) The Royal Infirmary of Edinburgh failed to properly and adequately assess Miss A’s condition on 20 January 2003: Conclusion

22. Radiological staff did not refer to the tests ‘excluding’ DVT although this was the discharge diagnosis given for Miss A. Medical staff appeared to ascribe Miss A’s symptoms to muscular injury without any evidence of this. The difference between ‘low probability’ and ‘exclusion’ is not one of semantics but of clinical accuracy.

23. Miss A was not given advice to return if her symptoms developed although I accept the Board’s comments that had she re-presented at RIE she would have been retested.

24. I consider that Miss A’s discharge diagnosis of 'muscular injury' and 'exclusion', rather than 'low probability', of DVT was not supported by the evidence. I do not consider this affected the treatment Miss A received from the RIE although it may have had an impact on her further treatment at the RAH (detailed in (c)).

25. For these reasons I partially uphold this aspect of the complaint. In doing so I recognise the widespread view within the medical profession that the venogram is as accurate a test as possible. The adviser has commented that 'this is a very sad case of a young woman dying from an illness which is difficult to diagnose due to the often few symptoms. This has occurred before, and will occur again.' I accept this view and its implications for the effective treatment of DVT. I acknowledge that this fact is of no comfort to Mr and Mrs C whose principal motivation in pursuing this complaint has been precisely to avoid a recurrence of their own tragedy for any other family. Any recommendations from the Ombudsman must recognise that there is a limit to what medical science can currently achieve. However, it is important to ensure that everything that can be achieved is achieved.

26. In light of this conclusion the Ombudsman recommends that the RIE review the information – both written and oral – that is currently made available to patients who have been reviewed for possible DVT. The Board should consider revising the DVT Management Protocol to include specific guidance on oral information to be given to patients about continued or progressing symptoms and consider the use of a Patient Information Leaflet for discharged patients. In particular the Ombudsman asks that thought be given to the avoidance of the phrase 'exclusion of DVT' when this exclusion is not currently achievable. The Ombudsman also asks for a report on this review and its outcome. The Ombudsman notes that venography is no longer used as a standard diagnostic test by the RIE, but recommends that the events of this case are discussed at an appropriate multi-disciplinary team meeting to highlight the limits of the available tests and the need for technical accuracy in communication.

(b) GP 1 failed to refer Miss A to an appropriate Acute Care facility on 22 January 2003

27. Mr C complained that the GP did not advise against Miss A attending the RAH which had no vascular surgeons and suggest instead a more appropriate choice of hospital with staff of sufficient experience.

28. In response to my enquiries the RAH provided me with a copy of their Protocol for Management of suspected DVT. The adviser reviewed this and considered it to be consistent with good practice in management of suspected DVT.

29. The adviser commented that at the time Miss A was reviewed by the GP on

21 January 2003 it was only one day since the negative finding of the venogram. Miss A's pain had worsened but her symptoms had not changed. The adviser considered the actions of the GP were reasonable in the circumstances and that the information passed on to the RAH doctor by the GP on 22 January 2003 was consistent with Miss A's discharge note from the RIE.

(b) GP failed to refer Miss A to an appropriate Acute Care facility on February 2004: Conclusion

30. Based on the medical advice I have seen I am satisfied that the GP's actions were consistent with accepted good practice. While the RAH was not a specialist unit for treatment of DVT it was an appropriate facility for an initial referral and diagnosis. I do not uphold this aspect of the complaint.

(c) The RAH failed to properly and adequately re-assess Miss A's condition on 22 January 2003

31. In response to my enquiries the Argyll and Clyde NHS Board stated that if a patient's test for DVT was negative but they continue to have symptoms then it was normal practice to re-test after one week. The Board also provided me with a copy of the DVT Clinical Assessment Form used by the RAH. This form adopts the Wells Test as the primary screening tool. The Board advised me that this form has been in use in the Accident and Emergency department since January 2002. The Board response indicated that Miss A would have scored a low probability of DVT in the Wells assessment test. Mrs C has told me that she was with Miss A at all times and does not recall this advice being given.

32. I can find no evidence in the medical record that the Clinical Assessment Form was used by the doctor treating Miss A. I note that the form indicates that a low probability score should be followed by a d-dimer blood test and reassessed according to this result. This did not happen in Miss A's case despite the Board's comment that Miss A's symptoms indicated a test result which would have made this the next course of action. The Board also commented that Miss A was given appropriate advice regarding any development of her symptoms.

33. The adviser commented that it was in line with standard good practice for the hospital doctor to contact Miss A's GP and discuss the previous test results. The adviser noted that it is clear from the medical records that the team at the RAH considered the diagnosis of DVT but rejected it solely on the grounds of investigations performed elsewhere two days previously. The adviser

expressed concern that the doctor at the RAH apparently accepted the view that a DVT had been excluded despite the impossibility of this ever being the case and the contrary views expressed by the patient. The adviser commented that this was unsatisfactory but that many doctors would find it understandable because of the lack of any completely accurate test. The adviser expressed a concern that Miss A was clearly a competent individual capable of giving a clear history but her view that she had not sustained any muscular injury was not given sufficient notice. He noted that when a patient re-attends it is not about the time since the last admission but about listening to the patient.

34. Both the RIE and the RAH stated that it is normal practice to re-test after one week if symptoms persist. I would note that Miss A suffered her fatal embolism less than a week after presenting at the RIE. The adviser had commented that there can be no clear timescale for re-testing. He considered that in any event a patient re-attending should mean listening to the patient and re-assessing the situation rather than applying a prescriptive time period.

(c) RAH failed to properly and adequately re-assess Miss A's condition on February 2004: Conclusion

35. I do not have any evidence to conclude that had Miss A been re-tested in line with the RAH Assessment Form her DVT would have been detected and the tragic outcome would have been averted. I do find that the Assessment Form was not used when there was good medical reason to do so. I conclude that there was a failure to provide an objective second opinion based on a misunderstanding of the accuracy of tests performed. I note that this misunderstanding occurred several times throughout Miss A's care and in several settings. I am very concerned that Miss A was apparently left with the overall impression that she was not being taken seriously and that her confidence in her own view of her condition was sufficiently undermined that it prevented her re-attending after her visit to RAH. I uphold this aspect of the complaint.

36. In light of this conclusion the Ombudsman recommends that the RAH audit cases of suspected DVT presenting at Accident and Emergency to ensure that there is compliance with the use of the DVT Clinical Assessment Form. The Ombudsman also asks for a report on this audit and its conclusions. The Ombudsman recommends that the events of this case are discussed at an appropriate multi-disciplinary team meeting to highlight the limits of the available tests, the need for technical accuracy in communication and what processes

should be adopted when reaching a second opinion.

Additional Concern

37. Miss A's medical notes indicated a number of differences in the care pathways of the different hospitals involved in her care. The RIE stated they would have re-tested Miss A had she represented although I note that no advice was given to Miss A in this respect. The RAH would have waited a week to re-test but contend that they did give advice to represent. The Boards used different screening and diagnostic tests and neither offered patients written information.

38. Both Boards have provided evidence of good procedures and protocols. The adviser commented that the record-keeping at both hospitals was of a high standard.

39. The different hospitals had different approaches to the management of suspected DVT. Based on the medical advice I have seen both approaches are consistent with accepted good practice although the lack of written patient information was unhelpful. However, I am concerned that from a patient perspective such differences can cause confusion and in this instance undermined the confidence of Miss A to re-present when her symptoms continued. The difference in retesting times gave rise to another missed opportunity to reconsider Miss A's condition. I note that DVT is not an uncommon condition and it is of concern that these events are unlikely to be unique within NHS facilities in Scotland. I can see no evidence of an integrated approach to management of suspected DVT in NHS Scotland and conclude that this was significant in this case.

40. In light of this concern the Ombudsman will be drawing this matter to the attention of the Scottish Executive Health Department and NHS Quality Improvement Scotland and ask that they consider the need for Scotland-wide guidance on the management of suspected DVT. In light of her recommendations in paragraphs 26 & 36 the Ombudsman will also ask that consideration be given to the need for a Patient Information Leaflet to be integrated into any guidance.

30 May 2006

Annex 1

Explanation of abbreviations used

the GP	Miss A's family general practitioner
Mr C	The complainant – Miss A's father
Mrs C	Miss A's mother
Miss A	The aggrieved
the RAH	The Royal Alexandra Hospital, Paisley
the RIE	The Royal Infirmary of Edinburgh, Edinburgh

Annex 2

Glossary of medical terms

D-dimer	a blood test used to screen for DVT
DVT, deep vein thrombosis	a blood clot (thrombus) that develops in a deep vein, usually in the leg
Embolism (pulmonary)	clot breaks away and travels up the vein to block a blood vessel (in the lung)
Plethysmography	blood pressure cuffs are placed on the legs to determine the pressure at which the veins are filled or emptied, so that obstructing blood clots can be identified
Venogram	produced by injecting a dye that can be seen on an x-ray into a vein on the top of the foot. The dye flows with the blood and fills the veins of the leg, thigh, and pelvis. An obstructing blood clot in one of these veins can be seen on an x-ray as a dye-free area within the vein
Volterol	a pain relieving drug
Wells Test	a scoring system for symptoms and based on the predictive value of these symptoms assess a probability of DVT