

Scottish Public Services Ombudsman Act 2002

Report by the Scottish Public Services Ombudsman of an investigation into a complaint against North Glasgow University Hospitals NHS Trust (the Trust)

Complaint as put to the Ombudsman

1. The account of the complaint provided by Mr R junior was that on 22 March 2001 his father Mr R, aged 90, was admitted to Glasgow Royal Infirmary (the hospital) with a history of vomiting and diarrhoea. This resolved and he was discharged on 30 March. On 1 April Mr R was readmitted (to a different ward of the hospital) with diarrhoea and dehydration. He was diagnosed as having a clinical infection caused by *Clostridium difficile* but attempts to control this by the use of metronidazole (Flagyl - an antibiotic) failed. It was decided to change his treatment to vancomycin. This was prescribed on 20 April and Mr R junior was told it had to be made up specially by the hospital pharmacy which caused a delay. Mr R died during the early morning on 21 April.

2. The matters investigated were that:

- (a) Mr R did not receive any antibiotic treatment after being given metronidazole on 17 April;
- (b) there was a delay between the first mention of the possible use of vancomycin (12 April) and the date on which it was prescribed (20 April); and
- (c) following the writing of the prescription on 20 April, there was a further delay before the vancomycin became available.

Investigation

3. The statement of complaint for the investigation was issued on 24 July 2002. Comments were obtained from the Trust and relevant documents, including Mr R's clinical records, were examined. Evidence was obtained

from a Consultant Physician (the Consultant), a Specialist Registrar (the Registrar), the Trust's Chief Pharmacist, the Pharmacy Manager and Service Manager, and a Ward Manager. One of the Ombudsman's professional advisers – a Superintendent Pharmacist – provided advice. His report is reproduced in its entirety in paragraph 16 below. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked. The glossary at Appendix A explains the medical terms used in this report.

Clinical background

4. Clostridium difficile is an organism which is commonly present in healthy people and does not normally give rise to problems. However, it does present a significant risk for patients whose health is already compromised in some way, as in Mr R's case. Flagyl is a brand name for metronidazole, which is an antimicrobial agent (an antibiotic) for the treatment of infections, including Clostridium difficile. Vancomycin is a relatively toxic antibiotic and must be used with care but it is indicated for use against potentially life-threatening infections that cannot be treated with other, less toxic, antimicrobial drugs. It is thus a second-line treatment for infection with Clostridium difficile. In cases of bowel infections, such as Mr R's, vancomycin should be given orally because it is not effective for such conditions when given intravenously.

Evidence of Mr R junior

5. In correspondence with the Trust and the Ombudsman **Mr R junior** said:

'... I went in in the afternoon on the afternoon on Friday 20 April ... [to] administer the medicine ... the Staff Nurse ... said [the vancomycin] was not available – out of stock and would not be in until midday ...'

'... [The Registrar] told us on the Friday [20 April] my father could die if he did not get this medication [the vancomycin]. This medication should have been available [...] not have to wait 24 hours when it was too late.'

'My father's drug was not in stock the night before he died. I was put off with another excuse that it had to be made up.'

Trust policies and procedures

6. The hospital's 'Care of the Elderly' Directorate antibiotic policy (which has since been superseded by a Trust-wide policy) stated that the policy's aim was to provide guidelines for the therapy of the more common infections in elderly patients and that, although it was not prescriptive or comprehensive, compliance with it was an important aspect of the Trust's infection control policy. It suggested that the policy should be adhered to unless a medical microbiologist had been consulted. The guidelines for *Clostridium difficile* treatment included:

'[Give] metronidazole ... [orally or intravenously if oral not possible] for 7–10 days. If failure to respond, stop metronidazole for 48 hours and then repeat course. If further treatment required: vancomycin ... Treat relapses with metronidazole. Do not send repeat stool specimens to check for clearance – clinical response is important.'

Extracts from Mr R's medical records

7. Entries in Mr R's **clinical notes** include:

'3/4/2001 ... continues to have diarrhoea. Continue IV [intravenous injection] amox[icillin*] further 24 [hours] then [change to] oral. Stool c/s [culture and sensitivity test] awaited (sent today). To commence oral Flagyl ...

[* Amoxicillin is an antibacterial drug, which Mr R was already taking for a suspected urinary tract infection.]

'5/4 ... Verbally and physically aggressive ... Continue Flagyl ...

'6/4 ... Not complying with medication ... Still passing loose ... stools ...

'7/4 ... still passing loose stools ...

'10/4 ... Diarrhoea persists. Continues on Flagyl (?compliance) ...

'11/4 ... Continues to have loose stools ... Non-compliant ... Continue metronidazole ...

'12/4 ... [Clostridium difficile] diarrhoea – on Flagyl ... Physical + verbal aggression to medical/nursing staff ... Refuses examination. Loose stools continue ... If diarrhoea continues change to vancomycin next week ... [signed by the Registrar]

'16/4 ... Continues on Flagyl. To change to vancomycin if diarrhoea persisting - ??IV access ... [signed by a Senior House Officer - the Senior House Officer]

'17/4 ... Still having loose stools. Apyrexial [not feverish] ... Has had about 12/7 [12 days] of Flagyl. Will not allow obs[ervations] to be performed therefore IV access impossible. To stop Flagyl. To repeat stool c/s. To attempt to recheck bloods ... [signed by the Senior House Officer]

'18/4 ... Diarrhoea persists ... Repeat stool c/s result awaited. To commence oral vancomycin pending result. [signed by the Senior House Officer]

'19/4 ... Still loose stools ... Abusive ... Off all antibiotics at present ... [Clostridium difficile] stool sent yesterday. If positive [start on] vancomycin (if will take it) ... Could I speak to family this afternoon? [signed by the Registrar]

'20/4 ... [ward round] Bowels remain loose ... To commence vancomycin pending stool c/s result ... [signed by the Senior House Officer]

'20/4 ... Spoke in detail to sons. They are aware of ... probable continuing [Clostridium difficile] ... Aware of guarded prognosis. They are keen to supervise vancomycin delivery to patient as they feel they will have more success than nursing staff. I have agreed to this and informed Staff Nurse looking after him. [signed by the Registrar]

'21/4 ... time of death [certified at] 07:03 ...'

8. Mr R's **nursing notes** include:

'3/4 ... Patient refused to let SHO [Senior House Officer] site a venflon. IV antibiotic withheld – some given orally with much encouragement ... Remains ... verbally abusive when attending to patients needs ...

'3/4 ... patient unmanageable for IV infusion ... Verbally and physically aggressive towards nursing staff when being attended – hitting out and swearing at staff ...

'6/4 ... Refusing medication this morning ... [12 noon:] Medication (antibiotic) changed to liquids as patient spitting out tablets ...

'8/4 ... Aggressive to nursing staff ... Very aggressive when being attended ...

'18/4 ... Patient refused venflon insertion. Sub cut[aneous] not viable due to patient wish of self harm injury ...

'19/4 ... Ward round [the Registrar] – await stool specimen culture result. For an iv antibiotic if positive. To try subcut[aneous]. Please ask son to see [the Registrar] at todays pm visiting. If not available ask him to make an appointment to see him ...

'20/4 10 am ... Seen by [Senior House Officer] and commenced on vancomycin.'

'20/4 3.30pm ... Son spoken to by [the Registrar] – sons are in agreement that patient should be given antibiotics. [The Registrar] has given sons permission to come to the ward morning and evening to give patient medication to ensure that same is taken ...'

The Trust's response to the statement of complaint

9. In a written response to the Ombudsman the Trust's **Chief Executive** included:

'... letters [from the Trust to Mr R junior during the Trust's investigation of the complaint] dated 13 June 2001 and 30 November 2001 incorrectly inferred that it was intravenous vancomycin that was requested when in fact it was oral vancomycin and this is held as a

stock item within the central pharmacy (although not a ward held item) therefore does not require to be specially prepared. I can only apologise for this misinformation and would ask that you convey the Trust's unreserved apologies to [Mr R junior].

'As far as can be ascertained the requisition for the vancomycin was written on the 20 April 2001 at some [time] in the early afternoon. The requisition ... was not marked urgent. I am advised that we cannot track exactly when it arrived in the pharmacy. The transaction log ... confirms that it was processed at 9.40 am on 21 April 2001 ... there is no evidence of non availability of oral vancomycin in the pharmacy at this time.

'... had the requisition been received late on 20 April, normal practice would be for a member of pharmacy staff to check if the prescription was urgent for that evening, although it cannot be verified that this happened on this occasion.

'... [Mr R] received his final dose of metronidazole on 17 April. The casenotes indicate on 19 April that medical staff were awaiting the results of a stool sample prior to commencing him on vancomycin, these results were available on 20 April.

'It is acknowledged that the possible use of vancomycin is first mentioned on 12 April and not actually prescribed until 20 April. During the intervening period [Mr R] was on a course of metronidazole which ... would normally be prescribed in the first instance to control this type of infection ...

'... this short delay, if in fact there was a delay in receiving the vancomycin would not however have been clinically significant. I ... acknowledge that it must have been distressing for [Mr R junior] to know that medication had been prescribed for his father although had not been provided prior to his death. The Trust regrets any upset this has caused.

'With regard to the particular aspects of the complaint under investigation, The Trust does not accept that the complaint is justified.'

Evidence of the Trust staff

10. The Trust's **Service Manager** told the Ombudsman's investigator in writing:

'[The vancomycin] was ordered on the 20th April 2001. Following discussion with the nursing staff, I was informed that the request for vancomycin was telephoned to the Pharmacy Department. This was followed by a paper request ... The nursing staff reported that there was a requirement for this drug to be reconstituted in Pharmacy and therefore it would not have been expected to be delivered until, either late that evening, or the following morning. This information led us to believe that there had not been a significant delay. At a later date, when investigating a further issue, it became evident that the vancomycin had been prescribed in capsule form and should have been readily available ...'

11. The **Ward Manager** of ward 20/21 provided a statement during the Ombudsman's investigation that included:

'Any registered nurse can transcribe drugs onto a pharmacy requisition form. Requisitions were sent through the hospital postal system carried by porters. Drugs were then delivered to the ward again by porters ...

'Mail was lifted from the wards at 3 hourly intervals ... It would be noticed on the drug round that the drug was not available. If medical staff had highlighted a need for a drug to be obtained urgently, then a member of staff would have delivered the requisition and waited for the drug to be available to bring back to the ward.

'The vancomycin was not prescribed on the morning ward round as [the Senior House Officer] was still awaiting the result of a stool specimen, sent to the lab. The drug was not ordered until that afternoon. If the drug was in stock I would have expected it to have been delivered later that afternoon. It was not uncommon for drugs to take longer, particularly at the weekend. Had the medical staff

wanted the drug to be started right away, they would have asked for it to be obtained urgently.

'[A Staff Nurse – the Staff Nurse] spoke with Mr [F]'s son at the evening visit and as the drug had not been delivered to the ward before 5pm (Pharmacy closing time), [the staff nurse] informed Mr [F] (junior) that it would be delivered before 12 midday on Saturday (Pharmacy closing time). [The Registrar] was informed by [the Staff Nurse] when the requisition was sent to the Pharmacy that the drug would probably not be available until the next day. This was following [the Registrar's] discussion with Mr [F]'s son.'

12. The **Registrar** said that Mr R's condition had been deteriorating primarily, although not solely because of an ischaemic left foot. The Registrar wrote in the clinical notes for 12 April that Mr R should be switched from metronidazole to vancomycin the following week if the diarrhoea continued. He decided not to repeat the course of metronidazole probably because, on balance, he felt it would be better to try vancomycin rather than another round of metronidazole as the diarrhoea was persisting. Mr R's metronidazole was stopped on 17 April which meant that, in line with the policy, he should have had a 48 hour antibiotic break from 17 to 19 April but vancomycin was not prescribed until 20 April. On 20 April the Registrar spoke to Mr R junior and his brother about how best to administer the vancomycin given the difficulties the staff had administering Mr R's medication either orally or intravenously. It was agreed that his sons would attend twice daily to assist. The Registrar decided on that basis that the best way to administer the vancomycin was orally so that Mr R could not pull out the intravenous equipment. He had no recollection of being told by the Staff Nurse that the drug would probably not be available until the next day and noted that there was no reference to this conversation in the nursing notes. He thought it unlikely that he would have agreed to this delay. The Registrar told Mr R junior and his brother of Mr R's poor prognosis but he would not have said that Mr R could die if he did not get the vancomycin. He acknowledged that there had been some delay in the prescribing and receipt of the vancomycin. However, he believed that the outcome for Mr R would not have been different even if he had received vancomycin on 19 April.

13. **The Consultant** said that although the antibiotic policy suggested two courses of metronidazole with a 48-hour break in between before trying vancomycin, it could be argued that it was appropriate to switch to vancomycin if the first course of metronidazole did not produce a successful response. Diarrhoea could stop, giving the impression that a drug had been successful but could then restart indicating that it had not been successful after all. This made it difficult to know when a treatment for diarrhoea was having effect. He presumed metronidazole was stopped on 17 April to provide a 48-hour break. He thought the reason for the 48 hour break could be to clear the previous antibiotic from the patient's system and give the system time to settle. He felt there were arguments both for and against such a break.

14. The Consultant said that the vancomycin was prescribed on 20 April apparently during the Senior House Officer's ward round at about 10:00 am. He would have expected nursing staff to have made the necessary arrangements, informing the Senior House Officer if there was any problem. For a prescription written in the morning, he would normally expect a dose to be available and given to the patient the same evening. However, he did not consider that a dose given on the evening of 20 April would have prevented Mr R's death the following morning given that, by then, Mr R had had diarrhoea for some weeks and had been admitted to hospital twice during that time because of it.

15. The hospital's **Chief Pharmacist** and **the Pharmacy Manager** confirmed that vancomycin was not an item held in stock on the hospital wards and had to be ordered from the pharmacy. The vancomycin for Mr R was to be given orally as capsules and had not had to be made up specially in the pharmacy. The transaction log which I have seen, showed that on 19 April 2001 the balance of vancomycin capsules in stock was 117 and the balance left after Ward 20/21 were supplied was 97 capsules. The transaction log also showed that the prescription was processed by the pharmacy at 9:40 am on 21 April.

Report of the Ombudsman's professional assessor

16. I now set out the assessor's report:

Matters considered

(i) To confirm that Mr R did not receive any antibiotic treatment after 17 April and consider whether this was clinically sound.

(ii) To consider the issues involved in the prescribing of the antibiotic vancomycin and whether there were delays in reaching this decision that were of clinical significance.

(iii) To establish why there was a delay between the time of prescribing vancomycin and the time when it would have been available for administration to Mr R and to consider whether this delay was of clinical significance.

Basis of report

(iv) This report is based on documents provided by the Ombudsman's investigating officer. These include: clinical notes; nursing records; prescription charts; pathology, haematology and microbiology test results; copies of relevant parts of the hospital's manual of procedures for the procurement, storage and distribution of medicines; the pharmacy records relevant to the period under investigation; the hospital antibiotic policy for the care of the elderly directorate which was in place at the time; and a recent Trust document 'Prescribing guidance for doctors' published in June 2002 for use Trust-wide. I attended interviews with medical and pharmacy staff at the hospital, conducted by the Ombudsman's investigator, and I visited the pharmacy department in the hospital.

Background

(v) Mr R, a patient of 90, had enjoyed reasonable health until 1999 when he had a stroke which resulted in left side weakness. It was possible at that time that he had had an acute arteroseptal myocardial infarction. Cognitive impairment, a heel sore and second-degree heart block were diagnosed. The clinical notes also include a CT brain scan that confirms marked cerebral atrophy. A series of ECGs show evidence of marked myocardial ischaemia. Overall, the clinical picture, starting in 1999, is complex. Subsequently an ischaemic foot developed, the origins of which I consider are most likely linked to the stroke in 1999.

(vi) On 22 March 2001, Mr R was admitted to hospital with a history of vomiting and diarrhoea. He received symptomatic treatment and was discharged home a week later.

(vii) On 1 April (within two days of his home discharge), Mr R was readmitted and was found to be pyrexial. There was evidence of recurrent diarrhoea. Although not clinically dehydrated at this time, he was not drinking, he was confused and had significant and deteriorating cognitive impairment. He was aggressive towards hospital staff, who found him a difficult patient to care for.

(viii) On 2 April, a stool sample was taken which indicated the presence of the bacterium *Clostridium difficile*. This was recorded in a report dated 4 April that was sent to the ward. A note on the report said that a high level of toxin was found in the specimen.

(ix) On 5 April at midday, Mr R was started on a course of an antibacterial agent, metronidazole, with a 400mg dose to be given three times a day by mouth using an oral suspension. This treatment continued until the last dose at breakfast time on 17 April. On two occasions during this time Mr R refused the dose.

(x) Further stool samples were taken on 3, 12 and 18 April, all of which showed the presence of *Clostridium difficile*. The sample taken on 3 April was reported as showing a high level of toxin in the specimen whereas the other samples were said to show low levels of toxin.

(xi) On 20 April, Mr R was prescribed the antibiotic, vancomycin, with a 750mg dose (according to the prescription charts) to be given by mouth twice a day. On 21 April, Mr R died in the early hours, before he had received any treatment with vancomycin.

Opinion – Complaint (a)

(xii) The original decision to treat Mr R with metronidazole 400mg orally for a *Clostridium difficile* infection was in accordance with the hospital's antibiotic policy. An initial seven to ten day course of treatment is specified, with a clinical review at the end of that time. Both the Consultant and the Registrar said they would expect the antibiotic policy to be followed. The

Registrar said that neither he nor his colleague, the Senior House Officer, had consulted a medical microbiologist about treating Mr R.

Comment In respect of the choice of drug, the length of treatment and the clinical review, the antibiotic policy adopted by the hospital is at least similar to that in use in most hospitals throughout the UK. Therefore, the decision to commence treatment with metronidazole on 5 April was entirely justifiable on clinical grounds. Policies and procedures are to help staff to work consistently within evidence-based practice. However, there is an expectation that more senior staff should consider the appropriateness of applying a policy with total rigour and for them to be mindful of the need to tailor clinical decisions to judgements around individual circumstances. Indeed, the introduction to the hospital antibiotic policy states that it is 'neither prescriptive nor comprehensive' and invites staff to consult the duty microbiologist at any time for advice, concluding by stating, 'Compliance with these guidelines is an important aspect of the Trust's Infection Control Policy.'

(xiii) The prescription charts and notes show that the first dose of metronidazole was administered orally at midday on 5 April, with the last being given at breakfast time on 17 April 2001. The Registrar confirmed this during interview. The clinical notes do not say why the decision was taken to stop antibiotic treatment, neither could the Registrar throw any light on the matter, other than it was in accordance with the antibiotic policy. The antibiotic policy states, 'Give metronidazole for 7-10 days. If failure to respond, stop metronidazole for 48 hours and then repeat course' (ie with metronidazole for seven to ten days). Vancomycin is specified as a prescribing option if further treatment is required beyond the second course of metronidazole. The antibiotic policy also says 'Do not send repeat stool samples to check for clearance- clinical response is important.'

Comment The antibiotic policy was not carried through in three main respects. Firstly, the 'antibiotic holiday' was extended from the 48-hour period required by the policy to what would have been 96 hours by the time Mr R received another dose of an antibiotic. Secondly, instead of repeating the course of treatment with metronidazole, the decision was taken to use vancomycin. I will return to consider the prescribing of vancomycin later on in this report. Thirdly, although the clinical staff should perhaps not be criticised for sending repeat stool samples, it is quite evident from the nursing notes and test results that the clinical response to treatment for

Clostridium difficile was poor and that Mr R was becoming clinically dehydrated.

(xiv) It should be noted that, if the antibiotic holiday had lasted only the required 48 hours, Mr R could have had four doses of vancomycin by the morning of 21 April.

(xv) The Registrar said at interview that Mr R had been treated with metronidazole for 12 days but this is not accurate. Mr R had in fact been treated for ten full days with metronidazole, from breakfast time on 7 April until breakfast time on 17 April. The charts show that the first dose of metronidazole was at midday on 5 April but that the evening dose on that day was refused. The breakfast time and midday doses on 6 April were successfully given but the night time dose on this occasion was refused. Nevertheless, Mr R did receive a full course of treatment.

Comment The decision to allow Mr R a 48-hour antibiotic holiday was in accordance with the hospital's own policy. Is the policy a reasonable one? In the UK there is no uniform policy for patients who do not respond but the hospital policy is not unreasonable. There is little published data on antibiotic holidays and one could argue whether two days was long enough or whether four days was too long. A short antibiotic holiday could be useful to allow clinical staff to eliminate the possibility of fever or of diarrhoea caused by the antibiotics themselves. There is also some evidence that metronidazole can paradoxically encourage the growth of *Clostridium difficile* and that some patients are unable to produce antibodies, thereby becoming hosts for *Clostridium difficile*. However, an antibiotic policy that is reasonable for patients who are not severely unwell may be inappropriate if there are serious underlying clinical conditions, as in the case of Mr R. Due note should have been taken of the fact that Mr R had experienced diarrhoea since prior to 23 March, the date of his first admission to hospital, and that his condition was deteriorating. Under these circumstances it is questionable whether the decision to withdraw antibiotics on 17 April without first seeking advice from a microbiologist was clinically sound.

(xvi) At interview, the Registrar was asked to comment on the biochemistry test results for a sample taken and reported on 18 April and on the haematology results for the same date but reported on 19 April. He said the biochemistry showed that Mr R had been dehydrated (clinically) for six

days and that the haematology results gave a 'very reactive, "not very well", sort of picture'. The test results immediately prior to the ones for 18 April were for 12 April.

Comment It is unfortunate the decision to enter a period of antibiotic holiday was taken at a time when the condition of Mr R was deteriorating rapidly, especially as the Senior House Officer had no recent test results to confirm her clinical decision. In my opinion it is likely that the medical staff did not identify the increasing degree of dehydration soon enough.

Opinion – Complaint (b)

(xvii) The first mention of the possibility of prescribing vancomycin is in the clinical notes for 12 April when the Registrar wrote, 'If diarrhoea continues, change to vancomycin next week'. At interview, the Registrar said this was not written for any particular reason – for example because of any particular test results – he was merely noting something that was included in the antibiotic policy as an option for the future. The Registrar could not recall why vancomycin was chosen instead of a further course of metronidazole but he said that, on balance, vancomycin was better than another round of metronidazole.

(xviii) Both the Consultant and the Registrar said at interview, and the Consultant wrote in the clinical notes, that the stool sample taken on 12 April had returned as positive for *Clostridium difficile* but with low toxin levels. Both doctors implied that low toxin levels might have been indicative of an improvement in the infection.

Comment A very high number of patients (20-30%) have recurrent symptoms with *Clostridium difficile* and it is therefore unlikely that microbiologists would normally be consulted until multiple relapses had occurred, unless the policy said so. The Registrar and the Senior House Officer relied heavily upon the antibiotic policy but clinical considerations for the particular circumstances of Mr R should have overridden the policy, pending review and appropriate consultation.

(xix) No weight should have been attached to microbiology reports of high or low toxin levels – the only relevant fact from the test report was that the infection with *Clostridium difficile* was still in evidence.

(xx) Mr R was severely unwell and was becoming increasingly dehydrated. It is difficult to defend the decision to withdraw treatment with antibiotics on 17 April without at the same time prescribing either a second course of metronidazole, and/or a course of vancomycin, preferably to commence immediately but certainly not to delay beyond the 48-hour antibiotic holiday laid down in the policy.

(xxi) At breakfast time on 17 April, Mr R received his last dose of metronidazole. The antibiotic policy required further treatment to commence during the morning of 19 April. Acting on the note made by the Registrar, the Senior House Officer wrote in the clinical notes for 18 April 'commence oral vancomycin pending result'. It was not until 20 April that the prescription was written, for vancomycin 750mg twice a day.

(xxii) The antibiotic policy calls for vancomycin 125mg four times daily. There is nothing written in the clinical notes to say why the prescription was for a different frequency and strength of dose but it is assumed, because the sons were going to attend hospital to administer the drug, that a decision had been sensibly taken to reduce the frequency of dosing from four times daily to twice daily. Under these circumstances the strength of each dose should nevertheless have been 250mg, not 750mg.

Comment There is no indication in the notes to show why there was a delay in prescribing vancomycin beyond the expiry of the antibiotic holiday. There was no reason why it should not have been written up at the time the decision was taken to stop metronidazole. In this way it would have been possible to obtain a supply from the pharmacy in readiness for commencement of treatment in the morning of 19 April.

(xxiii) There is evidence that the Senior House Officer and the Registrar were unfamiliar with vancomycin. On 16 April, the Senior House Officer wrote 'Change to vancomycin ... ?? i/v access' which indicates she was considering administering it intravenously. It appears she was not aware at that time that vancomycin is inactive against gastro-intestinal infections when administered by the intravenous route. She also appeared to be unaware of the required dose for vancomycin when given orally. The Registrar seemed to share her confusion over the appropriate route of administration for vancomycin. At interview he said that he had called in the sons so he could consider how best to give the vancomycin because Mr R

kept removing intravenous lines, making it impossible to administer vancomycin intravenously. The use of vancomycin by mouth seemed only to be under consideration for this reason, yet this was the correct route of administration and is the one specified in the antibiotic policy.

(xxiv) From the pharmacy department I obtained a copy of a new guidance booklet that was published in June 2002, 'Prescribing guidance for doctors'. I was told this has been adopted throughout the Trust, of which the hospital is a constituent part. The Chief Pharmacist, was involved in drafting the guidance. It includes a section on prescribing for infections with Clostridium difficile which gives the standard treatment as being with metronidazole, '400mg orally eight hourly for 7-10 days (seek advice if the patient fails to respond or relapses).'

Comment The development of this booklet, with its guidance to seek advice in unresponsive cases, is to be welcomed. Also welcomed is the fact that annual review dates have been included in the procedure for publishing the guidance. It is to be hoped that the guidance has been adopted in full not only by those in management posts but also by those involved in providing care to patients on a day-by-day basis.

Opinion – Complaint (c)

(xxv) At interview, the Registrar said he believed the prescription for vancomycin was written between 10:00 and 15:30 hours on 20 April and that he would have expected Mr R to receive the first dose of vancomycin that evening. The pharmacy transaction log indicates that the vancomycin was made up in the pharmacy at 09:40 hours on 21 April and that the supply was made using vancomycin capsules 125mg.

Comment There is no indication in the notes, or on the prescription that there was any urgency in the matter, nor is the pharmacy requisition marked urgent.

(xxvi) The ward copy of the requisition itself is poorly written and calls for one box (of 20) vancomycin capsules and gives the strength as 750 mg, in accordance with the prescription. Yet, at interview I was shown the pharmacy copy of the requisition that seemed to indicate 250 mg as the dose. The system for ordering ward supplies of drugs carries a high risk of transcription error and of opportunity for misinterpretation of prescribing

decisions. The Chief Pharmacist told me that the procedures within the hospital are similar to those used throughout Scottish hospitals.

(xxvii) On 13 June, in a letter to Mr R junior, the general manager deals with the delay in providing vancomycin to the ward. He wrote, 'The drug is administered within a saline solution and reconstituted under sterile conditions within the pharmacy department. It is not available from ward stock. Having been ordered, I believe, sometime in the afternoon of 20th April, it would have become available from Pharmacy on the morning of the following day.'

(xxviii) At interview, the Chief Pharmacist at the hospital said that he had known nothing of the complaint being made by Mr R junior until after it had reached the Ombudsman. The Chief Pharmacist regretted that there had been no opportunity for him to comment on the supply of vancomycin to Mr R junior or on the suggestion that his department may have contributed to any delays.

Comment The general manager was wrong. The intention was to supply vancomycin as pre-made oral capsules, not in the form described by the general manager. Except for the statement that vancomycin was not available from ward stock that part of his letter was completely erroneous and requires no further comment in this report. It also raises clinical issues to the extent of providing an indication that poor internal communications exist within the Trust and at the hospital. Poor internal communications can and do have a serious and far reaching impact on clinical services.

(xxix) The Chief Pharmacist and the Pharmacy Manager explained how drugs were supplied to wards, either as stock items or as separately prescribed items for individual patients. They confirmed that vancomycin was not a stock item for the wards. They provided documents to show an audit trail for the supply of vancomycin for Mr R and they explained that the actual prescriptions are not sent from wards but that requisitions are written for non-stock items and it is these which are sent to the pharmacy.

Comment The requisitions did not have anywhere for signifying that any urgency was required. Although the Chief Pharmacist explained that the pharmacy department would respond to a request for an urgent supply, it was not clear how a prescriber would make his/her wishes known to the nursing staff, nor how that request would be passed to the pharmacy. There

is nothing in the clinical notes to suggest that the Senior House Officer had considered the situation of Mr R was urgent but there are general matters of principle which the hospital may wish to consider for the future.

(xxx) During the interviews it became clear that clinical pharmacy services to the wards were under resourced and that the professional culture within the hospital meant that involvement of pharmacists in multi-disciplinary settings was poorly developed.

Comment Poorly developed lines of communication, and a lack of full engagement of pharmacists within the clinical setting, did contribute to the delays in providing Mr R with vancomycin. However, these delays were not the fault of the pharmacy department or of its staff who responded within the expected time to a routine request for vancomycin. We were told that the ward staff had telephoned a request for vancomycin to the pharmacy before the requisition was sent to them. If the telephone call was made, there is no evidence that the purpose was to express any urgency.

(xxxii) The delay between the Senior House Officer writing the prescription and the time when the patient could have received a dose of vancomycin – ie from around 10:00 am to 3:30 pm on 20 April until the morning of 21 April – meant that only one dose was missed. This would have had no effect on the clinical outcome and was not a contributory factor in the death of Mr R.

(xxxii) The Chief Pharmacist informed us that the pharmacy department now has full involvement in a Trust-wide medicines management committee, at which clinical pharmacists are able to exert appropriate influence on the important processes within prescribing and the use of medicines. We were also told that a full review of pharmacy services, including a study of skill-mix, was currently under way which could lead to further changes in the near future in the way medicines are prescribed and used. The Pharmacy Manager has become involved in a lead multidisciplinary role, working with nurses to improve ward practices.

Comment Changes, either already in place or which may come about because of the various studies under way, have great potential to improve a number of key aspects of the pharmacy services within the hospital. Patient safety and appropriate use of medicines could be significantly enhanced if the Chief Pharmacist is able to implement changes in the way he outlined to us at interview.

Summary and conclusions

(xxxiii) I have carefully considered the information presented to me through the written evidence and during interview. I have dealt with the three clinical complaints, drawing out the facts for each that I have been able to ascertain.

(xxxiv) By publishing 'Prescribing guidance for doctors', the Trust has already taken action in an attempt to improve prescribing decisions. The decision to stop treating Mr R, although it can be criticised, was taken broadly in line with the antibiotic policy. Mr R was gravely ill. Although in my opinion the decision did not have an overall effect on the final outcome, I conclude that insufficient attention was given to the overall condition of Mr R and as a consequence the decision was open to question on clinical grounds. It is hoped that due note will be taken of these comments.

(xxxv) The delay which resulted in Mr R missing four doses of vancomycin similarly, in my opinion, did not affect the final outcome. However, work currently in progress within the pharmacy department could significantly improve patient safety in the future and will encourage consistency in medicines management.

Finding (a)

17. It is clear from the medical records that Mr R was difficult to nurse and there were considerable problems administering medication. On 4 April a report on a stool sample showed the presence of *Clostridium difficile*. On 5 April at midday Mr R was started on the antibiotic metronidazole which continued until 17 April when the last dose was given at breakfast time. The Trust's policy on infection control recommended a 48 hour antibiotic break then, if necessary, another course of metronidazole and, if the infection persisted, another 48 hour antibiotic break followed by a course of vancomycin. The policy suggested consulting a microbiologist before diverging from that plan. A stool sample taken on 18 April and reported on 20 April showed that *Clostridium difficile* was still present. However, the infection control policy, and the Assessor, say that it is not necessary to send stool specimens to establish whether the infection has cleared but to rely on the patients clinical response. On 20 April vancomycin was

prescribed. Mr R died in the early hours of 21 April before receiving vancomycin.

18. The question is whether it was appropriate to stop Mr R's antibiotics on 17 April. The Assessor has advised that hospital policies exist to help staff but staff must tailor their clinical decisions to individual patients circumstances. He pointed out that the hospital policy included that it was not 'prescriptive or comprehensive'. He considers that the policy's suggestion of a 48 hour antibiotic break was not unreasonable but the need for, and length of, breaks was open to debate. It was not necessary to obtain and await the result of the stool sample taken on 18 April because it was clear from the nursing notes and test results that Mr R had responded poorly to treatment for the infection which was indicated by the biochemistry and haematology test results. He considered that the decision to discontinue antibiotics on 17 April was questionable given Mr R's poor condition at that time. In his opinion, which I accept, Mr R should have been started immediately on another course of antibiotics or at least started on another course after 48 hours. That is, at the latest, a further course of antibiotics should have been started in the morning on 19 April in which case Mr R would have received 4 doses by the evening of 20 April. I am advised that even if Mr R had received these four doses of antibiotics this would have had no effect on the clinical outcome and was not a contributory factor in Mr R's death. I uphold this complaint to the extent that Mr R should have received antibiotics at the latest at breakfast time on 19 April. However, I hope that Mr R junior will take some comfort from the Assessor's view that although there were failings these did not hasten the death of his father.

Findings (b)

19. I considered whether there was a delay between the first mention of the possible use of vancomycin and the date on which it was prescribed. The Registrar recorded on 12 April 'If diarrhoea continues, change to vancomycin next week'. The Senior House Officer recorded on 18 April 'commence oral vancomycin pending result [of stool sample]'. The Assessor noted that there was no indication of why there was a delay in prescribing vancomycin beyond the 48 hour antibiotic break period, that is beyond, breakfast time on 19 April and that there is no reason that it could not have been written up 'to commence in 48 hours' at the time when metronidazole was discontinued. However, I note that the prescription was written on

20 April, the same day when the stool sample report confirmed that *Clostridium difficile* was still present. The hospital policy makes it clear that it is not necessary to send repeat stool samples and the Assessor has confirmed that there was other evidence to suggest that the infection was still present. The Assessor also noted that the Registrar and Senior House Officer considered giving vancomycin intravenously which, for a gastrointestinal infection such as this, would have been ineffective. I uphold this aspect of the complaint to the extent that, in terms of the Trust's policy, there was between about 24 to 30 hours delay (19 April to 20 April) before Mr R was prescribed another antibiotic which, in the main, seemed to be the result of an inappropriate decision to delay the prescription until the result of the stool sample was known.

Findings (c)

20. The Registrar thought that the prescription for vancomycin written on 20 April by the Senior House Officer was written between 10 am and 3.30pm. The Ward Manager said that the prescription was not written on the morning round as the Senior House Officer was still awaiting the result of a stool specimen. The Registrar has no recollection of being told that the drug would probably not be available until the next day and he would have expected Mr R to have received the first dose that evening. The requisition note is dated 20 April and was not marked urgent. It has not been possible to establish when the requisition note reached the pharmacy. It was processed by the pharmacy at about 9.40 am the following morning. The requisition was for capsules of vancomycin not intravenous vancomycin as the Trust told Mr R during the Trust's investigation of this complaint. The Pharmacy Manager confirmed that sufficient vancomycin capsules were in stock on 20 April. The Ward Manager said that she would have expected the drug to arrive in the ward that afternoon but it was not uncommon for drugs to take longer. However, if medical staff had highlighted a need for a drug to be obtained urgently then a member of staff would have taken the requisition to the pharmacy and waited for the drug. She said that the vancomycin was ordered in the afternoon on 20 April and it had not been delivered to the ward by 5.00pm when the pharmacy shut therefore a staff nurse told Mr R junior that it would be delivered on 21 April before midday when the pharmacy closed. Given that the Senior House Officer did not indicate urgency and the Assessor's advice that the delay would not have made a difference to the clinical outcome, I do not consider that there was

an unreasonable delay between the writing of the prescription and the availability of vancomycin. I therefore do not uphold this aspect of the complaint.

21. I should also draw attention to the assessors comments that there is clearly scope for errors in transcribing or interpreting information from prescription charts. I **recommend** that the Trust consider action which could help to reduce the potential for error.

Conclusions

22. I have set out my findings in paragraphs 17 to 21. The Trust have asked me to convey through this report - as I do - their apologies to Mr R junior for the shortcomings which I have identified. The Trust have agreed to implement my recommendation in paragraph 21.

Gillian Stewart
Acting Investigations Manager
duly authorised in accordance with
paragraph 11 of Schedule 1 to the
Scottish Public Services
Ombudsman Act 2002

19 September 2003

Glossary of medical terms

acute arteroseptal	this describes a particular type of myocardial infarction (see below).
cerebral atrophy	a wasting and loss of substance due to cell degeneration within the brain tissue.
clinically dehydrated	a sustained and severe reduction in the normal water content of the body (eg as a result of vomiting or diarrhoea), not being balanced by an appropriate intake. This leads to poor performance of some normal bodily functions and organs (eg kidneys).
cognitive impairment	poor performance of the mental processes of perception, reasoning and intuition.
ECG	electrocardiogram: a tracing that represents and measures the electrical impulses associated with heartbeats.
evidence based practice	clinical procedures of proven worth, based on evidence gathered by research and evaluation, which are intended to ensure consistency of care of the highest quality.
ischaemic foot	an inadequate flow of blood to the foot. It is a serious disorder, usually resulting from a narrowing or blockage of the arteries that supply blood to the foot.

myocardial infarction	the death of part of the heart muscle which has been deprived of an adequate blood supply by blockage in the coronary artery during a heart attack.
myocardial ischaemia	an inadequate flow of blood to the heart muscles (see above).
oral suspension	a type of medicine which is made in liquid form, being intended for taking by mouth.
pyrexial	feverish
second degree heart block	a condition generally caused by muscles of the heart being unable to co-ordinate the contractions in its different parts ('the chambers'), often as a result of an inadequate blood supply. Usually the pulse is slow and blood pressure is low.
venflon	an instrument which is attached to the skin to enable intravenous passage of, for example, drugs.