CORONERS ACT, 1975 AS AMENDED

SOUTH  *AUSTRALIA*

FINDING OF INQUEST

An Inquest taken on behalf of our Sovereign Lady the Queen at Adelaide in the State of South Australia, on the 18th, 19th, 20th and 21st days of February and the 12th day of March 2003, before Wayne Cromwell Chivell, a Coroner for the said State, concerning the death of Ruth Sophie Stoll.

I, the said Coroner, find that, Ruth Sophie Stoll aged 71 years, late of 85 Onkaparinga Road, Bridgewater died at Wakefield Hospital, Adelaide, South Australia on the 4th day of April 2001 as a result of massive acute haemolysis leading to severe anaemia and multi-system failure as a result of an incompatible blood transfusion.

1. Introduction

1.1. Ruth Sophie Stoll died on 4 April 2001 at 4:45am at the Wakefield Hospital, Adelaide. She was 71 years old.

1.2. Miss Stoll had undergone aortic valve replacement surgery in 1993, but had since developed an aneurysm (an abnormal dilatation) of the aorta above the aortic valve, which was liable to rupture.

1.3. Miss Stoll was admitted to Wakefield Hospital on 28 March 2001. On 29 March 2001 she underwent surgery performed by cardio-thoracic surgeon, Mr John Stubberfield, to replace the aneurysmal aorta with a Dacron graft.

1.4. There was a difficulty during the operation when the right ventricle of the heart was torn, leading to profuse bleeding. The blood loss was controlled and the operation proceeded from there without undue difficulty. Miss Stoll received six units of blood by way of transfusion as a result of this complication.

1.5. Mr Stubberfield described what transpired after the operation as follows:

> 'Following the procedure her heart looked quite sluggish and required significant amounts of Adrenaline to keep her blood pressure elevated. The more severe problem was an intense bleeding which appeared to be due to abnormal clotting factors which at the time we related to simply her blood loss before and after the procedure. After a prolonged period of time it was felt that the bleeding was controlled enough to close the chest although she was still not clotting normally. She was returned to the Intensive Care Unit in a fairly unstable state at that point in time. Over the next 48 hours clinically she was improving to the point where it was felt she was likely to survive.
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> Fairly suddenly on 3rd of April 2001 she deteriorated in the Intensive Care Unit and ultimately died at 4.55 a.m. on the 4th of April 2001 due to what appeared to be severe haemolysis of her blood, severe anaemia and multi system failure including the kidney, heart and lungs. The cause of this rather acute deterioration at that time was not apparent to Dr. Clayton who was essentially responsible for her care at that time.
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> During the period of rapid deterioration it was clear that there was great difficulty and in fact impossible to find compatible blood to transfuse her for her severe anaemia. Part of the investigative process at that time was to send blood off to the Institute of Medical and Veterinary Science for further haematological assessment. The investigation of the blood problem was continued on after Miss Stoll's death and indeed it was at this point that it became apparent what the actual problem had been.
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> It evolved that as part of the process of the blood work up at the Institute of Medical and Veterinary Science that the blood typing that was originally carried out for Miss Stoll's aortic valve replacement in 1993 was retrieved. This showed that she was Group O not Group A as had been indicated by the typing and cross matching for her current surgery at the Clinpath Laboratories at the Wakefield Clinic.
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> Putting all this together I believe and this is supported I think by the Haematologists at both the Institute of Medical and Veterinary Science and at the Clinpath Laboratories that there was a mislabelling of the blood originally taken at Clinpath Laboratories prior to Miss Stoll's current surgery and that the blood from some other person was labelled as Miss Stoll's blood. This of course was typed and matched as Miss Stoll's blood, but unfortunately turned out to be a completely different type altogether.
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> Subsequently all the transfused blood that she was given was Group A blood and this lead to what we now believe was a massive incompatible transfusion event ultimately leading to massive acute haemolysis, multi system failure and unfortunately, Miss Stoll's death. I believe this is the only possible explanation for the course of events.'
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> (Exhibit C3a)'

2. <u>Pre-operative procedures</u>

2.1. At the time of her surgery in 1993, Miss Stoll's blood was identified as Group O (see the Royal Adelaide Hospital casenotes, Exhibit C15).

2.2. On 26 March 2001, Miss Stoll attended the premises of Clinpath Laboratories Pty Ltd at the Wakefield Clinic, which is part of the Wakefield Hospital Complex. Clinpath is a tenant of Wakefield Hospital, and is an entirely separate organisation.

2.3. Miss Stoll was accompanied by her sister-in-law Mrs Roma Stoll. Another patient, Mrs Martha Kovendy and her husband were also present. The group was accompanied to Clinpath by Registered Nurse Susan Moore, cardiac rehabilitation coordinator at Wakefield Hospital.

2.4. RN Moore could remember taking Mrs Kovendy in her wheelchair to Clinpath, but could not remember taking Miss Stoll (Exhibit C7, p2). Mrs Roma Stoll said that she and Miss Stoll were taken to another area of the Wakefield Clinic first, and by the time they arrived at Clinpath, Mr and Mrs Kovendy were already there (Exhibit C6, p3). Mrs Kovendy gave evidence to similar effect (T10).

2.5. Blood was taken from Miss Stoll and Mrs Kovendy by Registered Nurse Sally Gilbert, who was employed by Clinpath in its collection centre at Wakefield Clinic. She was the only registered nurse on duty at the time.

2.6. The blood test request forms in relation to Mrs Kovendy and Miss Stoll give the time at which the blood samples were taken by RN Gilbert. In Miss Stoll's case (Exhibit C7a), the form is marked 1445, and Mrs Kovendy's form is marked 1500 (Exhibit C5a). As I have already mentioned, this contradicts the evidence of Mrs Kovendy and Mrs Roma Stoll who say that Mrs Kovendy arrived first.

2.7. RN Gilbert has no specific memory of taking blood from Miss Stoll or from Mrs Kovendy (Exhibit C8, p15). She said that she would have delivered Miss Stoll's labelled blood samples to the laboratory, duly marked, before dealing with Mrs Kovendy. In particular, she denied labelling both sets of samples at the same time (Exhibit C8, p34).

2.8. When she was interviewed by Senior Constable Paul Gross on 28 November 2001, RN Gilbert explained the procedure in taking a blood sample as follows:-

> 'A: The person comes in – the form, and you look at it and make sure they've signed it, the patient's signed it just basically for Medicare purposes. Got their Medicare number, that's basically it and you just make sure that – you ask them if they've fasted according to the test. You just make sure the form's right, and then you take

them into the little room and they sit down. You get them to say – spell their name and do all the – where they live, say where they live, their date of birth, so you've established that you've got the right person. So that's fine, you're happy with that and once again you just look at what tests need to do. Then you work out what tubes you need, so you got your tubes, you get – you look at their arm to get a suitable vein. Once you've done all that and you've explained to them what you're going to do, you wash your hands, you do all the technique, antiseptic technique, you wipe down their hand with a bit of metho and then clean it. Then you do all – you put the tourniquet on, take the blood, get them to hold cotton wool. While they're doing that, holding it down, putting the pressure, you then got your tube and you – from that – the form.

Q: From the form.

A: Form, you put in the details. Like their name and date of birth and the address – no, just the test. Their name, date of birth and what the tests were and put the bar code on, and once you've done all that, you just put a bit of tape on the cotton wool, they're finished. You put your samples in a plastic bag and you – they come out with you an you take it to the lab. You say goodbye, they'll wake out the door and you take these into the lab and they sort them out, and they do what they have to do.'

(Exhibit C8)

2.9. The correct procedure is set out in the Clinpath Nurse Procedure Manual (Exhibit C4d, page 9 of 45).

2.10. When she gave oral evidence, RN Gilbert described a different procedure:

> 'I get the patient to say their name, date of birth, address and if the spelling doesn't look clarifying I get them to spell it, if it's a foreign name or if I find I'm not happy with it I get them to spell it out so I can print it out.' (T110)

2.11. The Manual requires that the patient should spell his or her name in every case (Exhibit C45, page 9 or 45, paragraph 2). RN Gilbert acknowledged that she had signed a memorandum on 20 April 2001 acknowledging that she had read and understood these instructions. The memorandum states:-

> 'It is vitally important that all nurses are aware of their responsibilities in relation to patient identification and specimen labelling (refer to Nurse Procedure Manual).' (Exhibit C4c, document 5)

2.12. When RN Gilbert underwent retraining on 2 May 2001 (which was required for different perceived deficiencies in her technique), it was noted that she still failed to ask patients to spell their names on two occasions, which again was in breach of the protocol (see Exhibit C4c, document 6).

2.13. If RN Gilbert had complied with the procedures set out in the Nurse Procedure Manual, then the two sets of samples could not have been mixed up. Unfortunately, subsequent testing proves that they were.

2.14. As I have already mentioned from Mr Stubberfield's report, the Institute of Medical and Veterinary Science (IMVS) became involved in Miss Stoll's case when they were consulted as the State Reference Laboratory for abnormal blood group serology, after the doctors treating Miss Stoll were unable to find compatible blood with which to transfuse her. The Head of Diagnostic Scientific/Technical Services, Division of Haematology, at the IMVS, Mr Kenneth Davis, outlined their investigations as follows:-

> 'On the morning of 4 April 2001 at about 0300 hours we received a referral request from Clinpath Laboratories at Wakefield Street, subsequent to a request to them to march further units of blood for the patient in question. When they received this request they actually detected a lot of abnormal tests results which they could not ascertain the cause for, so at that time, they forwarded it on to us. We are in fact the State Reference Laboratory for abnormal blood group serology, so that's how the process was initiated.
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> Our practice then is to go through a fairly well predetermined set of investigative processes to try and determine what is the problem, when other laboratories find it difficult or impossible to select compatible units for transfusion. That normally involves, as a standard practice, putting the patients sample up against a range of what we call, "reagent red cells", which have different antigen patterns on them and in that way the antibodies that are presumably causing the problem can usually be detected.
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> In our investigation it became clear that this particular patient did have a number of complicating antibodies in the sample that we had received on the 4th and after considerable investigation it was determined that she had definitely two antibodies against particular antigens which she herself would obviously lack, because normally that's the process with your immune response, you produce antibody against something you don't possess yourself. The complicating factor that was more puzzling was the fact that in comparison to her determined ABO blood group, we found fairly high levels of an antibody, namely Anti A, which for someone who was supposedly group A should not have been present. This was confirmed by the request for information by Clinpath at Wakefield Street about the blood groups of the products that she had been transfused, which were confirmed to us to all have been blood group A, including red cells, fresh frozen plasma and platelets. So there was no evident infusion of this Anti A from any of the blood products she received. This confirmation of the products that she had received therefore let us with this distinctly unusual observation that a person of her blood group should have such a high level of an antibody against her supposed ABO group.
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> In view of this inconsistency, we looked at our own transfusion history database and in the initial search could find no history on the particular patient in question to give us any clues. However we did make enquiries into our archived pathology database and discovered that this lady had actually been a patient in the Royal Adelaide Hospital

(RAH) in 1993. The normal requirement for transfusion laboratories is to archive all their historical data for a minimum of twenty years, so we went to our archived history file, which is actually kept by State Records out at Gepps Cross, and were able to find a request for blood for a cardiac procedure in the RAH in 1993. The evidence on that request determined that on her admission to the RAH in 1993 she was in fact blood group O and not blood group A. This seemed to be the answer to the puzzlement that we had determined in the investigations that we undertook and this was confirmed by going to the patients case file and looking at the historical reports that were archived therein.

At this point it seemed to us that what had occurred, was that the blood sample collected initially on this lady was in fact not from her and was from somebody who was blood group A and not the patients own blood group, blood group O. This finding was felt to explain convincingly the presence of this untoward findings of anti A in a group A person.

The laboratory investigation essentially took place over two days, because of it's complexity, and the clue to what was considered to be the answer to the more difficult problem of the unusual anti A, was determined late on the 5th of April. This was communicated to Dr. Malcolm Green, a Haematologist at Clinpath Laboratories, as to the suspected cause of this case and a written report was submitted to him on the 8th of April. I rang Dr. Green and advised him of the findings we had determined, due to the patients history at the Royal Adelaide Hospital, with the suggestion that in fact the major part of this transfusion problem had in fact been due to an incompatible ABO transfusion, based on the historical blood group from 1993 at the RAH and the pre-transfusion sample which we in fact tested here during our investigations.' (Exhibit C14)

2.15. In addition to the testing in April 2001, on 28 November 2002 Mr Davis tested the remaining spare sample which had been taken from Miss Stoll on 26 March 2001. This also confirmed that the sample labelled Miss Stoll bearing a barcode number 6954373 was Group A (when we know that she was actually Group O), and the sample labelled Mrs Kovendy bearing a barcode number 6954376 was Group O (when a test conducted on 14 April 2001 disclosed that Mrs Kovendy was actually Group A - Exhibit C14a, p1).

2.16. There is no room, on these results, for the theory that the samples were mixed up after they were delivered to the Clinpath Laboratory by RN Gilbert. Mr Davies told me that, in his opinion, that possibility had been eliminated (T341). If the samples had been correctly labelled by RN Gilbert, then the tests conducted on 28 November 2002 would not have reproduced the anomalous results. The samples must have been in the wrong containers to start with.

2.17. Mrs Kovendy's evidence

Mrs Kovendy gave evidence as to her memory of the process undertaken by RN Gilbert when she obtained a blood sample on 26 March 2001 as follows:-

> 'Before the nurse took my blood she said, "Can you tell me your name and date of birth?" She then took my blood and she turned around to a desk and I saw her write on the vials, the glass tubes. I couldn't see what she wrote on the tubes. Then she asked me to sign the form. I then saw her open a plastic bag, there is one part where you put the tubes and the other part where you put the form, and she put the tubes and the form in the bag and sealed it. She then put the bag in a collection trolley that was nearby. I did not see any other bag or tubes in this trolley. I saw the nurse write on the request form but I did not see her write anything on the bag. This whole procedure took about five or six minutes. The nurse then left the room carrying the plastic bag containing the blood and went through a door behind the reception area. I also left the room bud didn't see Mrs. Stoll in the waiting area, I was then wheeled back to Sue Moore's office.' (Exhibit C5)

2.18. RN Gilbert denied that there was any 'trolley' into which she put blood samples (T157).

2.19. With all respect to Mrs Kovendy, if her blood went with the glass tubes marked with her name and date of birth on them, then those tubes would have contained Group A blood. In fact, the evidence of Mr Davis, which I have already outlined, establishes that the tube marked with Mrs Kovendy's name which was tested on 28 November 2002 contains Group O blood, which is Miss Stoll's blood group. Mrs Kovendy's evidence cannot be correct.

2.20. Ms Fuller, counsel for RN Gilbert, sought to cast doubt on the conclusion that the error occurred at the time of sampling by pointing to the fact that there had not been a detailed investigation of the Clinpath Laboratory procedure, and that the 'chain of evidence' in relation to the blood samples from Miss Stoll and Mrs Kovendy could not be established. Miss Fuller also submitted that the evidence of Mrs Kovendy was the only direct evidence before me that shed any light on RN Gilbert's procedures on 26 March 2001, and that Mrs Kovendy supports RN Gilbert's position that no procedural error took place.

2.21. While I acknowledge the force of those submissions, it seems to me that the only possible explanation for these events which is consistent with RN Gilbert's position is that the samples from both Mrs Kovendy and Miss Stoll (four samples each) were deliberately switched in the laboratory. The error cannot have been the result of

inadvertent error in the laboratory. The pre-transfusion samples were still in the same test tubes, labelled and initialled by RN Gilbert, after the event – they had not been decanted into other containers for testing.

2.22. In my opinion, the possibility that all eight of these samples had been deliberately interfered with in this way is so remote as to be almost fanciful. There is not the slightest evidence that anything like that could have occurred.

2.23. In all those circumstances, I find on the balance of probabilities that an error occurred during the time when RN Gilbert was taking blood samples from Mrs Kovendy and Miss Stoll. Mr Davis postulated two ways in which the error could have occurred. Firstly, RN Gilbert could have pre-labelled the sample containers for both Mrs Kovendy and Miss Stoll, and then put the blood in the wrong set (perhaps as a result of an identification error). Secondly, RN Gilbert could have filled two sets of unlabelled containers with blood, and then mislabelled them subsequently. It is not possible to find which of these errors may have occurred, nor is it necessary to do so. I accept the evidence of Mr Alexander, the Chief Executive Officer of Clinpath, that if the protocol established in the Nurse Procedure Manual had been complied with, the error could not have occurred (T296).

2.24. Role of the Clinicians

In case it might have been suggested that the clinicians who were involved in Miss Stoll's surgery on 29 March 2001 should have somehow noticed the grouping and cross-matching error and taken remedial action before the transfusion took place, I heard evidence from Dr Rex Pearlman who administered the anaesthetic. Dr Pearlman is a very experienced consultant anaesthetist.

2.25. Dr Pearlman confirmed that Miss Stoll's casenotes were not available during the operation because her previous surgery had been performed at the Royal Adelaide Hospital. He said the casenotes are not usually retrieved unless the patient advises that a particular problem occurred during the previous operation (T194). He told me that even if the casenotes were available, it is unlikely that he would have checked them in order to verify the grouping and cross-matching results. He said the performance of the blood transfusion services had always been 'exemplary' (T203). He said that the results of the group and cross-match are usually not seen until the

morning of surgery. He said that it would only be in the event that he noticed a discrepancy with a previous record that the 'alarm bells' would ring (T209).

2.26. Mrs Roma Stoll told me of a conversation between her sister-in-law and RN Moore on 26 March 2001. She said that Miss Stoll was seeking assurance that her casenotes from her previous operation at the Royal Adelaide Hospital in 1993 would be present during the upcoming operation, and that RN Moore told her that they would be available to the doctors during the operation (T39). RN Moore said she had no memory of any such conversation (T77). She did not arrange for the casenotes to be retrieved.

2.27. The evidence from Dr Pearlman indicates that even if the casenotes were present during the operation, they would not have alerted the clinicians to the error in blood grouping. I do not consider that it is necessary to pursue this matter further.

2.28. While it is always desirable in any clinical situation for the clinicians to have access to the patients' casenotes, I accept that in this case it is unlikely that reference to the casenotes would have changed the outcome.

2.29. I find on the balance of probabilities that the availability of the casenotes on the morning of 29 March 2001 would not have alerted the clinicians to the fact that an error in the group and cross-match testing had been made. After the operation, Miss Stoll's condition improved, and it was not until 3 April 2001, when she suddenly deteriorated again, that a blood grouping anomaly was suspected, by which time it was obviously too late to affect the outcome.

3. Conclusions

3.1. I find that Miss Stoll died on 4 April 2001 at Wakefield Hospital, Adelaide, South Australia as a result of massive acute haemolysis leading to severe anaemia and multi-system failure as a result of an incompatible blood transfusion.

3.2. I find that the incompatible blood transfusion occurred because blood samples taken from Miss Stoll and Mrs Kovendy on 26 March 2001 for the purposes of grouping and cross-matching were inadvertently mislabelled.

3.3. I find that if the Registered Nurse who took the samples had complied with the Nurse Procedure Manual prepared by her employer, Clinpath Laboratories Pty Ltd, the error would not have occurred.

4. Recommendations

4.1. I accept Mr Alexander's evidence that he and his senior staff at Clinpath have agonised over the question of how an incident like this can be avoided in future. The incident obviously has shocked them, since such an event has never occurred before in Mr Alexander's long career (T231).

4.2. Mr Alexander pointed out that Registered Nurses have tertiary qualifications and are expected to have 'more than a basic understanding' of the issues involved. He said that the necessity for strict compliance with the protocols should have been obvious (T227-228). For this reason, he was anxious not to make the protocols more detailed.

4.3. It must also be kept in mind, however, that any system which relies upon human beings is susceptible to human error. Even the most highly trained and competent professional person can make a mistake from time to time. It is noted that if a transfusion becomes necessary during an operation, the blood products are cross-checked by two independent people to guard against error. No such cross-check is adopted at the time the blood products are collected for grouping and cross-matching.

4.4. Central database

Mr Alexander suggested that there should be a central blood group register established on a computer database, to which information from all laboratories, both public and private could be uploaded. This database could then be consulted during every group and cross-matching procedure as a check against error.

4.5. As far as I am aware, the feasibility of this suggestion has never been examined in detail. I presume that the database would need to be operated by a Government agency, presumably within the Department of Human Services in South Australia. It would also be desirable that any such database should have interstate links. I am sure that there would be privacy and other concerns which would need to be considered. I am unable, on the information before me, to express an opinion as to whether any

such system would be feasible, but I mention the suggestion for the consideration of others.

4.6. New Request Form

Mr Davis showed me a new request form used for grouping and cross-matching tests which has been developed by the IMVS for the Royal Adelaide Hospital (Exhibit C14i). In particular, the form has a specific section in which the person 'drawing blood' must certify that the samples were labelled immediately, and that a proper identification process has been undertaken. The section must be signed by the collector and by a witness, whether it be the patient or another staff member.

4.7. Mr Alexander was vigorously opposed to the idea of creating a separate request form for grouping and cross-matching. He pointed out that, among other difficulties, a separate form could cause difficulty if doctors or nurses use the wrong form, particularly in an urgent situation. (T262).

4.8. I accept that the Royal Adelaide Hospital form, while not dealing with the deliberately non-compliant person, may well be useful in that it reminds the collector to avoid inadvertent errors. Mr Davis said that the form was being trialled at the Royal Adelaide Hospital, and I commend the results of the trial to the attention of regulatory agencies.

4.9. New Guidelines

Mr Davis also produced a copy of Guidelines which have been developed by the Australian and New Zealand Society of Blood Transfusions Inc in 2002 (Exhibit C14h). These Guidelines recommend the approach taken by the IMVS in relation to the request form. The Guidelines also provide detailed procedures for sample testing and labelling which, in fairness, are similar to Clinpath's Nurse Procedure Manual, and are in one respect less detailed (Clinpath requires that the nurse ask the patient to spell his or her name, whereas the Guidelines simply require the patient to state their name).

4.10. I was told by Mr Davis that these Guidelines are likely to be adopted by the National Association of Testing Authorities and will be taken up when all laboratories undertake their biennial accreditation processes in due course.

4.11. Role of Carers

One further issue which I think is well-illustrated by this case is the under-utilisation of the carer. Both Mrs Roma Stoll and Mr Kovendy were there to provide support and assistance, and yet both of them remained outside the room while the blood collection process took place.

4.12. Patients facing very serious heart surgery, or any surgery for that matter, can be expected to be highly anxious, and susceptible to communication errors. The presence of another person (who need not witness the actual venepuncture) would substantially reduce the risk of any such errors occurring.

4.13. Other Cases

I have been made aware of three cases which were the subject of inquests conducted in New South Wales by Ms P J Staunton, Coroner. Her Honour delivered findings on 5 October 2001. The inquests involved the deaths of Beryl Sawicki (Matter No. 799/00), Antonina Malarbi (Matter No. 1027/00), and Norman Alan Baker (Matter No. 1126/01). The circumstances in those cases were different from the case before me, in that an identification error did not occur during the blood sampling process, but during the transfusion.

4.14. I was informed that these inquests led to the issue of a circular dated 10 October 2002 from the New South Wales Health Department entitled "Management of Fresh Blood Components". The only section of the circular relevant to the case before me is entitled "Collecting and Labelling of Specimens". This advocates the process now in place at the Royal Adelaide Hospital as described by Mr Davis, in that it requires double-checking of the specimen, and identification of the patient at the time of sample collection, by either one staff member and the patient, if appropriate, or two staff members (see Exhibit C14j, p2).

4.15. Having regard to all of these matters, pursuant to Section 25(2) of the Coroners Act I recommend as follows:-

- That the Guidelines developed by the Australian New Zealand Society of Blood Transfusions Inc, particularly in relation to the blood grouping and cross-matching request form, be adopted by all organisations engaged in blood testing;

- That Mr Alexander's suggestion of a central blood group computer database be further examined by the Department of Human Services;
- That protocols for blood collection incorporate an encouragement to collectors, where possible, to have a relative or carer present, so that the risk of communication difficulties with the patient is reduced.

Key Words: Blood Transfusion; Nursing Care; Hospital Treatment

In witness whereof the said Coroner has hereunto set and subscribed his hand and Seal the 12th day of March, 2003.

Coroner