

*External Inquiry into the adverse
incident that occurred at Queen's
Medical Centre, Nottingham,
4th January 2001*

by

Professor Brian Toft

BA (Hons) Dip Com Sci (Cantab) PhD

MInstD FIRM FIIRSM FIOSH Hon FICDDS

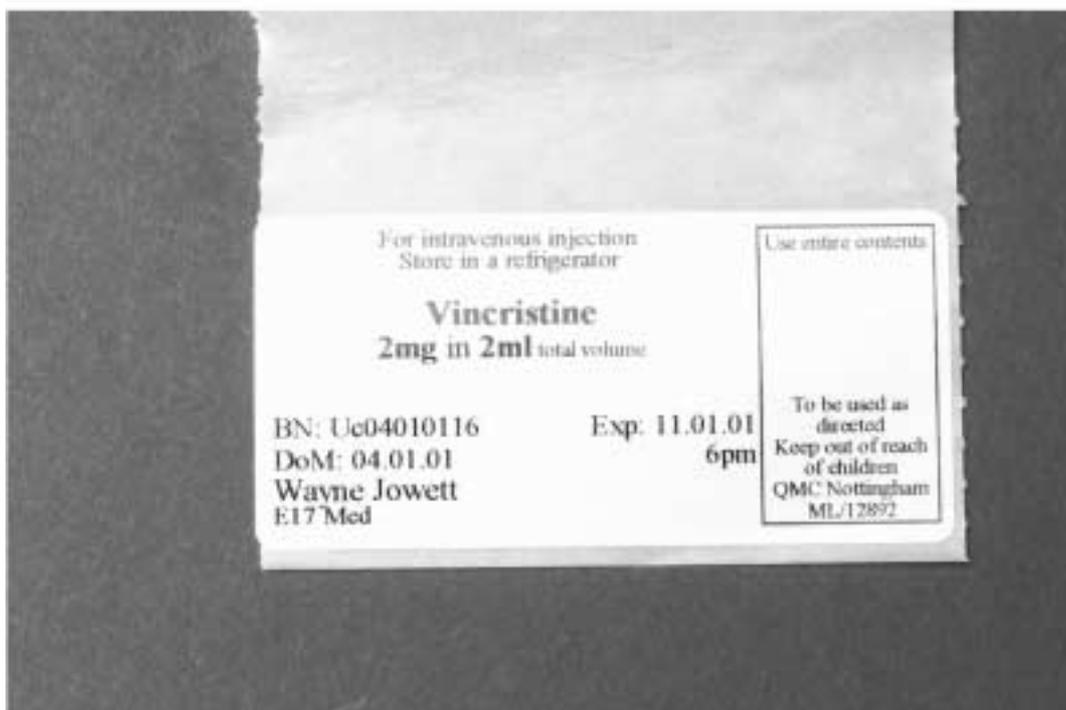
CONTENTS

Chapter 1: Introduction	9
Background to the adverse incident	10
The patient	10
Ward E17	11
Hazard awareness of Vincristine	11
Protocols	12
Labels	12
Packaging and supply of cytotoxic drugs	13
Protocols and guidelines	13
Nursing staff	13
Physical appearance of syringes containing cytotoxic drugs	13
Chapter 2: Provision of chemotherapy for the Day Case Unit	15
Sterile Production Unit	16
Dispensing Cytotoxic Drugs	17
Intravenous Administration of Cytotoxic Drugs	17
Intrathecal Administration of Cytotoxic Drugs	18
Senior House Officers	18
Codes of practice, Protocols and Guidelines	18
Specialist Registrars	19
Day Case Co-ordinator	20
Professional Experience of Staff Involved	20
Chapter 3: Chronology of events	23
Tuesday 2nd January 2001	23
Wednesday 3rd January 2001	23
Thursday 4th January 2001	24
Ward E17	24
Mr Jowett's prescription	24
Ward E17	24
Sterile Production Unit	24
Thursday afternoon	25
Collection of Mr Jowett's chemotherapy	26
Admission to Ward E17	26
Proceedings leading to the adverse incident	27
Chapter 4: Analysis	30
Tacit Assumptions	30
The medical team involved in the adverse incident	30
Senior Medical Personnel Ward E17	33
Nursing Staff Ward E17	34
Pharmacy Staff	35
Day Case Coordinator	37
QCM Drug Custody and Administration Code of Practice	37
Discussion	37

Chapter 5: Conclusions and Recommendations	40
Conclusions	40
The adverse incident	40
System Failures	40
Safety Culture	40
Operational practices	41
Protocols	42
Administration	42
Training	43
Communications	43
Technical	43
National Issues	44
Recommendations	44
Operational practices	44
Protocols	45
Administration	46
Training	46
Communications	47
Technical	47
National issues	47
References	49
Appendices	51

List of Plates

- Plate 1** A reconstruction of the labels affixed to the syringes.
- Plate 2** Photograph of a pre-filled syringe containing Vincristine illustrating the warning written in blue text.
- Plate 3** A photograph of two similar syringes to those used in the procedure.
- Plate 4** A reconstruction of how the two syringes would have looked in their respective packaging.
- Plate 5** Reconstruction of the bag of chemotherapy dispensed to Ms Shanahan.
- Plate 6** A reconstruction of an intrathecal procedure.



A reconstruction of the labels affixed to the syringes – Plate 1



A photograph of two similar syringes to those used in the procedure – Plate 2



Photograph of a pre-filled syringe containing Vincristine illustrating the warning written in blue text – Plate 3



A reconstruction of how the two syringes would have looked in their respective packaging – Plate 4



Reconstruction of the bag of chemotherapy dispensed to Ms Shanahan – Plate 5



A reconstruction of an intrathecal procedure – Plate 6

List of Appendices

- Appendix 1 Two lists of witnesses. Those who gave both verbal and written evidence to the inquiry held on 12th February 2001 at Queens Medical Centre Trust, Nottingham. A second list containing witnesses who provided written evidence but who were not called to give verbal evidence to the inquiry.
- Appendix 2 Medical Research Council Working Party on Leukaemia in Adults, Acute Lymphoblastic Leukaemia (UKALL Trial XII Protocol), Revised May 1995.
- Appendix 3 Diagram of Ward E17.
- Appendix 4 Ward E17 Procedure for the Administration of Systemic Chemotherapy.
- Appendix 5 Ward E17 Haematology Guidelines and Protocols.
- Appendix 6 SHO's Ward E17.
- Appendix 7 Mr Jowett's Chemotherapy Chart "Regular Prescription" section showing the list of drugs and the dates ordered for administration.
- Appendix 8 Mr Jowett's Chemotherapy Chart "Treatment Regime" section showing the word "Methotrexate".
- Appendix 9 QMC Drugs Custody and Administration Code of Practice section 10.4.
- Appendix 10 QMC Drugs Custody and Administration Code of Practice section 15, "Prescribing, Dispensing and Administration of Cytotoxic Chemotherapy".

Chapter 1: Introduction

At approximately 17.00hrs on Thursday 4th January 2001, Mr Wayne Jowett, a day case patient on Ward E17 at the Queen's Medical Centre Nottingham (QMC), was prepared for an intrathecal (spinal) administration of chemotherapy as part of his medical maintenance programme following successful treatment of leukaemia.

After carrying out a lumbar puncture and administering the correct cytotoxic therapy (Cytosine) under the supervision of the Specialist Registrar Dr Mulhem, Dr Morton, a Senior House Officer, was passed a second drug by Dr Mulhem to administer to Mr Jowett, which he subsequently did. However, the second drug, Vincristine, should never be administered by the intrathecal route because it is almost always fatal.

Unfortunately, whilst emergency treatment was provided very quickly in an effort to rectify the error, Mr Jowett died at 8.10am on the 2nd February 2001.

Following an Internal Inquiry at QMC into the circumstances surrounding the death of Mr Jowett, I was commissioned by Professor Liam Donaldson, Chief Medical Officer (CMO) for England and Wales to hold an External Investigation with a remit:

“To investigate the circumstances leading up to an intrathecal, rather than intravenous injection of Vincristine into a patient at the Queen's Medical Centre Nottingham (QMC) on 4 January and to report findings to the Chief Medical Officer.

“To advise the Chief Medical Officer on the areas of vulnerability in the process of intrathecal injection of these drugs and ways in which fail-safes might be built in.”

Subsequently, four Assessors, clinical experts who are highly regarded in their respective fields, were appointed to assist this inquiry. These were:

Dr Roger Buchanan, Consultant Clinical Oncologist, Royal South Hants Hospital.

Dr Peter Clark, Consultant Medical Oncologist, Clatterbridge Centre for Oncology NHS Trust.

Dr Max Summerhayes, Principal Pharmacist Oncology, Guy's and St. Thomas's Trust.

Mr Dickon Weir-Hughes, Chief Nurse & Director of Quality Assurance, The Royal Marsden Hospital (London & Surrey).

I would like to express my sincere thanks to each of them for the help and support that they have provided. However, the conclusions expressed in this report are my own and therefore, any errors are solely my responsibility.

Prior to commencing the formal hearing on the 12th February 2001, the inquiry panel visited Ward E17, side room 6 (the site of the adverse event), the Day Case Unit, Sterile Production Unit in the Pharmacy and 'B' Floor Pharmacy, from where the chemotherapy was dispensed, in order to gain first hand knowledge of the physical characteristics of each location, and to be taken through the sequence of actions that is believed to have taken place on the 4th January 2001. I would like to thank all those who assisted the inquiry panel at the different locations. The visits were extremely useful and helped to improve our understanding of the evidence that was presented.

Similarly, I would like to express my gratitude to Kathy Kirkwood, QMC Trust Secretary and Philomena Fox, QMC Trust Clinical Risk Lead, for their diligence in taking contemporaneous notes during the inquiry, providing a type written transcript of the proceedings for the panel and the additional assistance provided to me in clarifying a number of issues during the writing of this report. Finally, I would also like to record my appreciation to the staff of the Audio Visual Department at QMC for providing the photographs used in this report.

This report draws on the written statements that have been made, the findings of the Internal Inquiry (QMC, 2001) and the verbatim evidence of witnesses who attended the Inquiry on the 12th February 2001 (Appendix 1).

Background to the adverse incident

Actions within organisations are determined by the understanding that those who work in a particular environment have of that situation. People try to make sense of their organisational setting and then act in the belief that the assumptions that they have made are facts (Weick, 1995).

It is therefore imperative to understand the organisational setting in which the adverse incident took place. (Department of Health, 2000: 24).

The patient

Mr Wayne Jowett was born on the 13th February 1982. He was diagnosed with acute lymphoblastic leukaemia (ALL) in June 1999. Mr Jowett was being treated in accordance with the UK Medical Research Council's UKALL Trial XII protocol for adult patients who are under 56 years of age (Appendix 2).

In June of 2000, Mr Jowett's disease was in remission and he entered the maintenance phase of his treatment.

Mr Jowett's maintenance treatment consisted of receiving intravenous Vincristine, intrathecal Cytosine and oral Prednisolone every three months. He was also to take daily oral 6-Mercaptopurine (6MP) and weekly oral Methotrexate.

During this maintenance phase of his treatment, Mr Jowett was under the care of Dr Musuka, Locum Consultant Haematologist, and was seen on a monthly basis for assessment. On these occasions, blood tests would be carried out, chemotherapy provided as appropriate and he would be given his prescription. However, between June and December 2000, Mr Jowett missed two of his scheduled appointments and there was some concern that he may not have been taking his drugs.

Prior to 4th January 2001, Mr Jowett had last attended the Day Care Unit on the 22nd December 2000 when he had been seen by Dr Bethan Myers a Specialist Registrar. At that meeting, Mr Jowett requested that the invasive procedures of his intravenous and intrathecal chemotherapy be deferred until after the Christmas and New Year festivities. Dr Myers agreed to Mr Jowett's request and wrote in to Mr Jowett's clinical notes that the restart date for his chemotherapy would be "4.1.01."

Now, while this information had been transferred to the Ward Diary, it had not been entered into the Ward Manager's chemotherapy diary. As a result, Mr Jowett's chemotherapy had not, as was normal practice, been ordered in advance.

Mr Jowett missed his planned appointment to see Dr Musuka on the morning of the 4th January 2001 and did not notify Ward E17 of his intention to arrive that afternoon.

Ward E17

Ward E17 is a Haematology Unit that consists of a ward of 18 beds. There are six side rooms and three bays each of which contains four beds. There is also a Day Case Unit that is managed by a senior member of the nursing staff who is trained in the administration of cytotoxic chemotherapy.

Patients with a wide range of acute and chronic haematological diseases are also treated on the ward.

The medical staffing on the Unit consists of three Consultants, one part-time Staff Grade Doctor, one part-time Senior Registrar, two Specialist Registrars (SpR), and three Senior House Officers (SHO).

Each day a Consultant visits the ward and there is always a nominated Consultant available to give advice at all times. A Registrar is also scheduled to cover the ward work during the morning and afternoon of each weekday. The registrars rotate between Derby, Nottingham City Hospital and QMC.

The SHOs on the Unit are all ward based but also attend outpatient clinics. As part of their general training in medicine, SHOs rotate through the Haematology Unit every four months.

The nursing staff on the ward each weekday consists of:

- Two Registered Nurses and two Nursing Auxiliaries covering ward work on an Early and Late shift arrangement.
- A Staff Nurse trained in chemotherapy who works from 08.00hrs to 17.30hrs and is in charge of the Day Case Unit.
- There is also a Nursing Sister trained in chemotherapy who is the Ward Manager and works from 08.00hrs to 16.30hrs.

Additional assistance is also provided by:

- An in-patient assistant who acts as a Housekeeper and works from 08.00hrs to 16.00 hrs.
- Two ward receptionists one of whom is designated as the Day Case Unit coordinator and works from 08.00hrs to 17.00hrs.

It was an established routine for nurses to only participate in those ward rounds conducted by all the Consultants together and these were known as the “Grand Ward Rounds” (twice weekly). On other E17 Ward rounds, it was the stated duty of the SHO to handover to the nursing staff on completing the ward round.

The ward, whilst having an appointment system, also operates an “Open House” policy for patients. Thus, patients are encouraged to either contact the ward by telephone or go straight to Ward E17 if they believe they have a problem rather than sit in the Accident and Emergency Department waiting to be seen.

Hazard awareness of Vincristine

Provided Vincristine is administered intravenously (IV), it is a powerful and useful drug in the fight against leukaemia. However, if the drug is administered, in error, through an intrathecal injection (IT) the result is usually the death of the patient or if the patient does survive, then they typically suffer from severe neurological trauma.

The danger to patients through the inadvertent intrathecal administration of Vincristine is well known to those who manufacture the drug. As a result, the literature that comes with the product carries a warning to that effect. Likewise, there is literature published by the pharmaceutical and medical community such as *The Cytotoxic Handbook*, Third edition, Allwood *et al* (1997) and Department of Health (2000), which warn of the consequences to patients should Vincristine be inadvertently injected intrathecally. Furthermore, some previous incidents concerning these tragic accidents have been fully reported in the media and in medical journals.

Drawing upon the lessons learned from previous incidents, the medical staff at QMC put in place measures to reduce the risk of intrathecal administration of Vincristine. A number of which are described below.

Protocols

Because of the known danger associated with the inadvertent intrathecal injection of Vincristine, the "Acute Lymphoblastic Leukaemia Trial XII" (UKALL Trial XII, May 1995) protocol on which Mr Jowett's treatment was based was changed by the medical staff at QMC. The UKALL XII trial states that Vincristine (IV) and Cytosine (IT) should be administered on the same day (Appendix 2: 18). This part of the protocol was changed so that the drugs would be prescribed so as to be administered on different days thereby reducing the risk to patients. The amended protocol calls for patients to be given an intrathecal injection of their chemotherapy on the first day of their treatment and the intravenous Vincristine on the second.

Thus, if strictly observed this change in protocol should have prevented the two types of drugs prescribed for a single patient from being on the ward at the same time. However, as discussed later this did not always occur.

Labels

For the additional safety of patients, the label attached to any syringe, which contains Vincristine, produced by the QMC Pharmacy, states that the contents are "For intravenous injection". While a syringe containing a cytotoxic drug to be administered into the spinal column of a patient, is labelled "For intrathecal use". It should, however, be noted that the colour of the type on the label in both cases is 'black'. The type of font used on labels for both drugs is New Times Roman and the size of type used for the route of an injection is 7 point and normal type. The dose of a drug is in 9 point and **bold** type, while the name of the drug is in **bold** type but the size of type is slightly larger at 10 point. Thus, it is the name of the drug and the dose to be administered that is most prominent on each of the labels (Plate 1).

In neither case, are there any other identifying characteristics on the labels to denote that the drugs must be delivered by different routes. Only the words on the labels indicate the route by which a drug must be administered. The use of the same font for the labels and putting the name and dosage of a drug in bold and slightly larger type, in one sense, de-emphasises the significance of the route of administration. Bold type will also tend to catch the eye of someone reading a label rather than normal type. Thus, there are no strong visual cues to draw a reader's eye to the significance of the route of administration on labels produced by the QMC Pharmacy.

It is interesting to note that the manufacturer of the Vincristine used at QMC provide labels to be attached to their pre-filled syringes before being dispensed for use. These labels have the words "**Not for intrathecal use – For intravenous use only**". However, it was decided by the staff at QMC based on accepted 'best practice' not to use these auxiliary labels because the word "Intrathecal" is present. It was thought that, since Vincristine must be given intravenously, this had the potential to confuse someone carrying out the procedure and thus increase the risk of a patient having the drug administered by the wrong route.

Packaging and supply of cytotoxic drugs

Another way in which it was attempted to improve the safety of patients was through modifying the Pharmacy database, which is used to produce the syringe and packaging labels, so that only the three drugs used for intrathecal chemotherapy could be labelled for intrathecal use. The separate packaging and supply of intravenous and intrathecal cytotoxic drugs to the wards was yet another way in which an attempt was made by the Pharmacy to improve patient safety with regard to Vincristine. Some of these issues will be discussed in more detail in the section on the Sterile Production Unit (SPU).

Protocols and guidelines

Written haematological protocols and guidelines relating to intravenous and intrathecal administration of chemotherapy were also produced and are discussed in more detail in the section on Senior House Officers below.

Nursing staff

It was decided, as a matter of policy at QMC, that unless there were extenuating circumstances the only persons who should administer intravenous cytotoxic drugs to patients would be nurses who had undertaken specific training in their administration. This practice will be discussed later in the section on the Intravenous Administration of Cytotoxic Chemotherapy.

Physical appearance of syringes containing cytotoxic drugs

The physical appearance of a commercially available pre-filled syringe of Vincristine does differ in some respects from a syringe produced by the in-house Pharmacy containing Cytosine (Plate 2). For example, a commercially available syringe of Vincristine is made of glass and the protective cap at the bottom of a syringe is grey in colour. While a syringe produced by the QMC Pharmacy and containing Cytosine, would be made of plastic, and the protective cap at the bottom of a syringe is red.

Additionally, printed on to the glass on the side of a syringe containing Vincristine are the words “Vincristine Sulphate Injection 2mg/2ml NOT FOR INTRATHECAL USE” (Plate 3). It should be noted, however, that while those words are visible, following the attachment of a label to a syringe containing Vincristine the label does cover a portion of the total message.

Unfortunately, while there are a number of physical dissimilarities that can aid a physician to distinguish between a syringe that contains Vincristine and one that contains a drug to be administered intrathecally there are four visual similarities between the two syringes.

First of all, the syringes used to administer the two drugs can be of similar size, i.e. 2ml (Plate 2). Thus, the size of the syringes used in the procedure will not necessarily help to identify the route of administration to be used.

Secondly, the volume of drugs contained in a syringe for delivery by the intrathecal route can vary from 0.5ml up to 6ml. While a syringe containing Vincristine can contain up to 2.5ml of the drug. Thus, the volume of drugs administered by the IT or IV route could and in this case were similar as shown by their labels (Plate 1). Therefore, the volume of a drug in a syringe would not necessarily, provide a visual cue as to what drug it might contain.

Thirdly, this situation can be compounded because Cytosine and Hydrocortisone (drugs that are administered by the intrathecal route) and Vincristine have no individually recognisable colours, they are all clear liquids. Hence, both the volume and colour of two of the drugs that can be safely delivered by the intrathecal route can look identical to Vincristine. The exception to this is the drug Methotrexate which is also administered intrathecally. This drug is yellow in colour and consequently should be easily distinguishable from Vincristine.

Finally, the most dangerous physical aspect of all, in my opinion, is that a syringe containing Vincristine can also be connected to the spinal needle that delivers intrathecal drugs to patients. Clearly, once such a connection has been made the patient's life is in danger as there are no other safeguards in place to prevent the Vincristine from being administered.

Chapter 2: Provision of chemotherapy for the Day Case Unit

The typical method for ordering and receiving chemotherapy drugs for day case patients is as follows:

In the week before a given group of patients are due for treatment (typically a Thursday), the Ward Manager discusses their cases with a Specialist Registrar (SpR) or Consultant. All the drugs to be administered to each patient are written on their individual blue (in colour) prescription charts and a plan of work is drawn up for the following week. Thus, cytotoxic drugs that have completely different and potentially hazardous routes of administration are prescribed on the same prescription chart.

When cytotoxic drugs are prescribed on Ward E17, the routes of administration are also annotated on the patient's prescription chart. Vincristine will have the letters 'IV' after its name, likewise the name of a drug for spinal administration will have the letters 'IT' after its name. This is done in order to flag up that the two drugs must be administered by particular routes and is intended to serve as a safety precaution. However, initials can sometimes be unclear, particularly when hand written and they can be misread.

Another point to note is that for drugs which have to be administered by either the nursing or medical staff the dates on which a drug is to be administered is entered on to the prescription chart. Prior to a patient receiving their chemotherapy, the date of administration should also be checked.

On the day after the plan of work has been drawn up (Friday), the Ward Manager discusses it with the Ward Pharmacist. Following this conversation, the Ward Pharmacist takes the chemotherapy prescription charts to the Sterile Production Unit (SPU) in the Pharmacy where they are processed. A discussion of this set of procedures can be found in the section on the SPU below.

On the day of treatment, providing a patient is well enough to receive it, if the chemotherapy is not already on Ward E17, a member of staff telephones the SPU to ascertain if it is ready for collection. If the chemotherapy is ready for collection any member of ward staff available goes to the back hatch of 'B' Floor Pharmacy from where it is dispensed. The drugs are then taken back to Ward E17.

Once the chemotherapy is on Ward E17, it is stored in either a small refrigerator located in the Day Case Unit or in a larger one, which is situated in the Treatment Room (Appendix 3) until required for administration to a patient. In neither of these two refrigerators were there any arrangements for keeping drugs to be given by different routes of administration separate once they arrive on the ward. Nor could they be locked.

The Day Case Unit starts treating patients before the Pharmacy SPU 'opens' in a morning. Therefore, in an effort not to inconvenience patients it became common practice on Ward E17 to request that the SPU make up the chemotherapy the day before it was required and to arrange for it to be collected from the dispensary. It was then stored in one of the ward refrigerators over night.

Under such conditions it is not only possible to have cytotoxic chemotherapy drugs to be delivered by different routes of administration on Ward E17 at the same time for different patients, but also to have those same drugs on the ward for the same patient at the same time.

Sterile Production Unit

As noted earlier, following a discussion with the Ward Manager, the Ward Pharmacist takes the patients' prescription charts to the SPU. Once there, the Ward Pharmacist checks the accuracy of the prescription on each individual patient's chart against the established protocol and then enters the details from the prescription chart into the Cytotoxic Order Log.

Once details of a patient's chemotherapy have been entered in to the Cytotoxic Order Log, the Ward Pharmacist then takes the prescription charts, where patients had been prescribed oral medication, to the Dispensary so that those drugs can be dispensed.

Once details of a patient's chemotherapy have been entered into the Cytotoxic Order Log, the details are then transcribed by an experienced Assistant Technical Officer (ATO) on to each patient's Cytotoxic Worksheet. After the information has been transcribed, it is checked against the patient profile. This describes the full treatment protocol for each individual patient and the drug formula calculated.

A senior technician in the SPU then checks the formula entered on to the Cytotoxic Worksheet and, provided the order is correct, the drugs are prepared and made up in the SPU.

Once a patient's order is made up, it is labelled and a qualified Pharmacist then checks the order to ensure it is correct in all respects. The drug or drugs are then placed into the appropriate outer packaging, which is also labelled with the contents of the bag and a cytotoxic warning sticker.

Intrathecal drugs are always supplied in separate bags from drugs prescribed for administration by other routes. Copies of the labels attached to the chemotherapy are also affixed to the back of the Cytotoxic Worksheet. It should be noted that the physical packaging (clear plastic mini grip bags) of both intravenous and intrathecal syringes is exactly the same in its appearance. There are no visual cues as to what a package contains other than the labels affixed to it (Plate 4).

On the occasions that Vincristine and drugs for intrathecal administration were made up at the same time, it was common practice, by members of SPU staff, to deliver the drugs separately and at different times to 'B' Floor Pharmacy for collection by the ward. There was not, however, any explicit protocol, which stated categorically that this sequence of actions, was mandatory.

Thus, as already noted, if Ward E17 requested that a patient's full prescription of cytotoxic drugs be made ready for collection, regardless of routes of administration, at the same time, then typically the Pharmacy would comply with that request. The reason that the Pharmacy staff complied with such requests was because they did not want to be accused of compromising patient care. Clearly, this was not a situation envisaged when the medical staff of Ward E17 modified the UKALL XII Trial protocol.

When completed, the chemotherapy orders would be taken from the SPU to 'B' Floor Pharmacy where they were placed in a refrigerator to await collection by a representative from Ward E17. The usual method of storage if space was available was for drugs prescribed for intrathecal administration to be placed on one shelf and intravenous on another. Thus, there were no clearly demarcated areas for the two types of drug within the refrigerator. However, it was not always possible to put the drugs on separate shelves and in any case, it still meant that drugs intended for administration by different routes were in the same place, at the same time and, on occasions, for the same patient.

Having delivered the chemotherapy to 'B' Floor Pharmacy, the person who had transported the drugs from the SPU would then complete the "Collection of Specials and Chemotherapy from the Dispensary by Ward Staff" sheet. Details such as the Ward, patient's name, name of drug and route of administration (annotated IT or IV at the side of the name of the drug) would be entered after which the person delivering the drugs would initial the sheet.

Dispensing cytotoxic drugs

The procedure for obtaining drugs from 'B' Floor Pharmacy was for the Ward E17 representative wishing to collect chemotherapy to attract the attention of the Pharmacy staff by pushing a bell ring and then waiting for someone to attend the dispensing hatch. However, there was no one within the Pharmacy specifically assigned to answer calls to the dispensing hatch and consequently any member of the Pharmacy staff who happened to be passing or working near the hatch would answer the summons. Therefore, the hatch could be attended by someone who had no idea of the potential danger posed to patients by Vincristine and intrathecal drugs being in close proximity to each other.

Once someone attended the dispensing hatch, the person requiring chemotherapy for Ward E17 would then ask for the drugs of an individual patient or the ward as a whole. The person in the dispensary would then look in the refrigerator containing the chemotherapy and dispense the drugs requested. Before receiving the chemotherapy, the ward representative would sign or initial the 'Collection of Specials and Chemotherapy from the Dispensary by Ward Staff' sheet.

There was no requirement, however, for the person actually dispensing the chemotherapy from 'B' Floor Pharmacy to sign or initial the 'Collection of Specials and Chemotherapy from the Dispensary by Ward Staff' sheet. At this point, there was a clear break in the audit trail.

Having signed for the chemotherapy, the drugs would be taken back to Ward E17 and put in one of the refrigerators to await collection. In practice, all ward staff had access to both refrigerators and it was not unusual for doctors to collect their own chemotherapy from the refrigerators.

It should be noted at this point that, if three patients had each been prescribed three items of chemotherapy, it was common practice for the nine items to be dispensed packaged in three bags, i.e. one bag per patient containing the three items prescribed. Similarly, it was also accepted practice that drugs for intravenous administration, while individually packaged, would be sent to the ward packed together in one common bag for ease of transport.

Intravenous administration of cytotoxic drugs

If a patient is to receive intravenous chemotherapy then, in general, as noted above, only nurses with the appropriate training are supposed to administer it. Although, in practice, there are occasions when a patient sometimes requires chemotherapy when the Day Case Unit is shut, for example, on a weekend, and then an SpR with sufficient experience or a Consultant would administer it. However, in the vast majority of cases only a nurse with the requisite training will administer such chemotherapy to patients.

Thus, in the case of a patient arriving at the Day Case Unit requiring intravenous chemotherapy, first of all, a sample of the patient's blood will be sent for a Full Blood Count. This is to determine if the patient is healthy enough to receive their treatment. Once the results are known an SpR is informed and he or she will then make the decision as to whether or not the chemotherapy will go ahead. If a patient is fit enough to have their chemotherapy administered, a Ward E17 protocol entitled "Procedure for the Administration of Systemic Chemotherapy" is followed by the nurses who will be involved in providing treatment for that patient (Appendix 4).

It can be observed that the protocol used by the nurses who administer cytotoxic drugs is rigorous and specifically designed to try to ensure that human error is reduced to the minimum.

Intrathecal administration of cytotoxic drugs

Following assessment by a doctor and a satisfactory Full Blood Count, if a patient's chemotherapy is to be delivered intrathecally only an authorised SpR or Consultant may administer it. Also, because a lumbar puncture is required and this is a medical procedure, a doctor must perform it. Therefore, typically a Consultant or an authorised SpR will administer the chemotherapy but will often have the assistance of an SHO to carry out the lumbar puncture as part of their training.

Unlike the trained nurses when they administer intravenous chemotherapy, no detailed systematic written protocol, as noted above, was provided on Ward E17 for the medical staff although there were some guidelines and these are discussed later.

Senior House Officers

As part of their general medical training SHOs spend four months on Ward E17. On their arrival either the Ward Manger or a Senior Staff Nurse provides them with the following documents: 'Haematology Guidelines and Protocols' (Appendix 5) and 'SHOs Guide to Ward E17' (Appendix 6). Following which the SHO is given an explanation of how the ward is organized and where the other ward procedures and policies are to be found. It is also made clear at this time that the Consultants on the ward operate an 'Open Door' policy with respect to their junior staff and should be approached if there is any confusion. There is not, however, a formal 'induction process' and a new SHO like a new SpR will learn through practical experience.

Codes of practice, protocols and guidelines

There is a document entitled "QMC Drug Custody and Administration Code of Practice" published in summer 1998 and available to all staff. However, during the roll out process supervised by the Pharmacy this code of practice appears to have been brought principally to the attention of the nursing staff. The Consultant staff of Ward E17 were not aware that the document existed. Thus, the information that it contained was also not drawn to the attention of Dr Mulhem or Dr Morton. The code of practice contains vital information on numerous issues including good practice in relation to the prescription of drugs and the responsibilities of medical staff in relation to the safe preparation, checking, administration and recording of drugs.

With regard to the 'Haematology Guidelines and Protocols' issued on Ward E17, in the section entitled "Chemotherapy" it states, "There is a more detailed protocol for the administration of cytotoxics." However, the name of the document or where it might be located is not provided. Hence, it is difficult to see how anyone, if they did locate another document relating to the administration of cytotoxic chemotherapy, would know for certain that it was the one referred to in Ward E17's 'Haematology Guidelines and Protocols'.

Additionally, one of the bullet points in the section on chemotherapy states, "Always confirm chemotherapy bag or syringe corresponds with the prescription". But no detailed protocol is provided, as there is for nurses who administer intravenous chemotherapy, as to how this should or must be accomplished. Therefore, since the medical staff on Ward E17 were not aware of the QMC code of practice on drugs any check on a patient's chemotherapy carried out by them was based solely upon their professional experience, which in the case of a new SHO or SpR could be limited.

The section of the 'Haematology Guidelines and Protocols' concerning the administration of intrathecal chemotherapy states:

"Never mix intrathecal and intravenous chemotherapy on the same trolley or table.

Should only be given under direct supervision by Registrar.

Only Methotrexate, Cytosine (aka Cytarabine) and Hydrocortisone are given by this route.

It should never be given on the same day as IV Vincristine.”

Whilst the above guidelines do provide some information for doctors regarding intrathecal and intravenous chemotherapy, it is a little ambiguous. For example, doctors might interpret the phrase: “Never mix”, as if the intended message was that the two drugs should not be reconstituted together. As opposed to the actual objective, that the two types of drugs should never be on a table or trolley at the same time in case they are confused for one another.

Furthermore, there are two versions of the guidelines in circulation. In the edition provided to Dr Morton the last line of text, “It (intrathecal chemotherapy) should never be given on the same day IV Vincristine”, is missing. Thus, anyone reading that particular edition of the guidelines would be unaware that intrathecal injections should not be given on the same day as IV Vincristine.

Additionally, the guidelines do not make it clear as to whether or not an SHO may administer intrathecal chemotherapy.

Because an SHO only spends a short amount of time on Ward E17, they are considered to be a high risk and hence are not expected to administer cytotoxic drugs. But they may be, as noted earlier, expected to carry out the lumbar punctures required prior to an intrathecal injection as part of their training. The guidelines, however, do not mention the fact that an intrathecal injection of Vincristine is usually fatal. Hence, the enormity of the consequences of making such an error is not explicitly stated. Therefore, if the main source of explicit information regarding the dangers of Vincristine is in these guidelines it is doubtful that anyone could recognise the gravity of the situation if it should arise.

Specialist Registrars

The only explicit information on cytotoxic drug hazards given to a newly appointed SpR on Ward E17 is the same as that provided for a new SHO, except that they are also provided with a copy of the ‘Administration of Systemic Chemotherapy’ (Appendix 4). Similar to a new SHO, a new SpR is also issued with a list of the clinics that they are to attend.

The “induction process” on Ward E 17 for new SpRs is informal. During the first two weeks, a new SpR is allocated a more experienced SpR or Staff Grade Doctor to act as a Mentor. A new SpR is told to “shadow” the Mentor, however there does not appear to be any explicit definition of what such shadowing might consist of. Nor what the new SpR should do with their time when the Mentor is not present.

At the end of the induction period, there is no formal assessment by a Consultant to ascertain if the new SpR has in fact read all the ward protocols and understands how to apply them appropriately. The appraisal of a new SpR on Ward E 17 was based solely on what the person has been observed doing in practice by the Mentor and competent others.

A new SpR is told that they will have little or no clinical responsibilities over this shadowing period and that they should familiarise themselves with the Ward E17 and the laboratory protocols. Concomitantly, a new SpR is also advised that they should not carry out any medical procedures until a Consultant has satisfied him or herself as to their competency. But as we will see later, a new SpR does carry out some work virtually straight away on Ward E17 and thus the picture is a confusing one.

The training of a new SpR on Ward E17 is by way of experience, some formal teaching and serendipity. That is to say, the new SpR will attend ward rounds and bedside teaching will take place when the attending Consultant considers appropriate patients are on the ward. Likewise, when a patient presents a rare or particularly interesting disorder at the outpatient clinic SpRs will be invited to join the Consultants. Finally, there is teaching at lunchtime sessions on the ward and formal courses that they can attend.

As noted earlier, Consultants on Ward E17 have an "Open Door" policy and if there is any confusion they can be approached at any time for advice. However, confusion comes in degrees, from being not absolutely sure, to being completely unsure. Therefore, selecting the most appropriate level of uncertainty with which to solicit the advice of a Consultant or other senior member of staff may prove a moot point particularly for someone who has just joined the ward's medical staff.

Under the system described above there would appear to be some ambiguity as to a new SpRs initial responsibilities, duties and training.

Day Case Co-ordinator

The Day Case Co-ordinator fulfils a number of roles within the unit such as receptionist, administrator and as a courier for chemotherapy required for patients.

Despite transporting cytotoxic drugs from 'B' Floor Pharmacy to the Day Case Unit, the Day Case Co-ordinator did not receive any formal instruction regarding the danger created for patients when Vincristine and other drugs for intrathecal use are in close proximity to one another.

Professional experience of staff involved

Dr Mulhem

Dr Mulhem qualified as a physician at Damascus Medical School, Syria where he was awarded the degree MD in August 1991. He subsequently worked at hospitals in Syria until he came to the United Kingdom (UK) in August 1998.

After arriving in the UK, Dr Mulhem held a number of positions and for the eleven months prior to his appointment at QMC, he had been employed as an SHO in clinical and laboratory haematology at Leicester Royal Infirmary (LRI).

Prior to working at LRI, Dr Mulhem had not had any experience of treating patients with chemotherapy while in the UK. During the time in which Dr Mulhem worked as an SHO in the Haematology Department, he states that:

"The system for the administration of chemotherapy at Leicester was that drugs for administration intrathecally were never available on the ward at the same time as drugs for administration by another route. When I administered chemotherapy, only intrathecal drugs were in the chemotherapy box."

At LRI, the custom was to transport drugs for intrathecal administration to patients in a yellow box. Thus displaying to the doctor receiving it a clear and unambiguous visual cue as to what the syringe or syringes in the box should contain.

Dr Mulhem also makes the point that:

“When an SHO was undertaking intrathecal chemotherapy a Registrar would supervise...I knew that Vincristine was given intravenously, and was aware that it could only be given by that route. Although I did not know that intrathecal administration would almost invariably be fatal I understood that Vincristine should not be given by that route.”

It should also be noted that Dr Mulhem never had any kind of formal training to administer cytotoxic chemotherapy at LRI or at QMC. Thus, his knowledge of the protocols and procedures used in such treatments had been solely derived from the empirical experience that he obtained while in the Haematology Department at LRI.

Dr Mulhem took up his post as a SpR (Fixed Term Training Appointment) at QMC on Tuesday 2nd January 2001 and while he was an experienced SHO this was his first post as a Registrar.

Dr Morton

Dr Morton is a Registered Medical Practitioner who qualified with a BM BCh in 1999. Prior to his appointment at QMC, he had worked at several hospitals in the UK but never within a department that used cytotoxic drugs for the treatment of patients.

Dr Morton joined the staff of QMC in August 2000. His first post at QMC was working for Dr Simon Page in diabetes and endocrinology. He was transferred to the Haematology Unit at QMC on the 27th November 2000, thus at the time of the adverse incident involving Mr Jowett, Dr Morton had only been working on the Haematology ward for five weeks.

Dr Morton states that:

“I do not recall being taught about Vincristine as part of my undergraduate tuition. When I arrived in the Unit, there was no induction system to warn of the dangers in the use of Vincristine although I knew it was to be administered under supervision.”

He also points out that his:

“...previous experience of chemotherapy administration was limited. On a single occasion, I administered intrathecal Cytosine. That was in mid to late December 2000. I was supervised by a Staff Grade Doctor on this occasion. There was no nurse present.”

Moreover, Dr Morton had received no formal training in the administration of chemotherapy at the time of the adverse incident. Furthermore, as an SHO, he was not scheduled to attend any such training during his rotation on Ward E17, even though he was expected to attend and play an active role in the procedures that led up to the administration of intrathecal drugs.

Thus, when a member of the Inquiry Panel asked him:

“Were you aware of the need to check chemotherapy prior to administration?” Perhaps it was not so surprising that he replied, *“At that time I was not aware that it was my personal responsibility to check the drugs before giving them.”*

At the time of the adverse incident, none of the Consultants or the Ward Manager had any knowledge that Dr Morton had administered intrathecal chemotherapy under the supervision of a Staff Grade Doctor.

Dr Musuka

Dr Musuka qualified as a medical practitioner in Harare, Zimbabwe in 1992 and came to England in 1996 to carry out postgraduate training at QMC and Nottingham City Hospital. In March 2000, Dr Musuka completed his training when he became a member of the Royal College of Pathologists.

In April 2000, Dr Musuka returned to QMC as an SpR. In August 2000, as there was a vacant post for a Consultant in the Haematology Department, Dr Musuka was invited to accept the post of Locum Consultant Haematologist, which he did. It was in this capacity that he became responsible for the treatment of Wayne Jowett.

It should also be noted that, while Dr Musuka is experienced in prescribing chemotherapy, he has received no formal training in the practical administration of such drugs.

Sister Denise Crouch

Qualified, as a State Enrolled Nurse in 1978 and as a Registered Nurse in 1993, Sister Crouch also has additional qualifications in Oncology and Haematology. She joined Ward E17 in 1995 and became Ward Manager in 1997.

In her role as Ward Manager, Sister Crouch was aware of the danger associated with Vincristine and of the protocols and procedures that should be adopted regarding its custody and storage.

Staff Nurse Jo Vallance

Qualified as a Registered Nurse in February 1995, Staff Nurse Vallance has continued to work on Ward E17 since that date. Having successfully completed the 'Scope of Professional Practice' training package in the administration of cytotoxic chemotherapy in 1998, Staff Nurse Vallance has had three years of practical experience in the administration of intravenous chemotherapy. Consequently, she was aware of the danger associated with Vincristine and of the protocols and procedures that should be adopted on the ward regarding its storage and custody.

Chapter 3: Chronology of events

Tuesday 2nd January 2001

Upon his arrival at Ward E17 QMC, Dr Mulhem thought that it looked as if the ward staff were not expecting him. However, having been to the ward, Dr Mulhem then went to the Personnel Department to complete some paperwork after which he went back to Ward E17.

Some time between 13.00hrs and 14.00hrs, Dr Musuka (Locum Consultant) had an informal discussion with Dr Mulhem regarding his clinical interests and training requirements.

From 14.00hrs to 15.30hrs, Dr Mulhem was present at a Grand Ward Round with Dr Gould (Consultant), Dr Musuka and a number of other members of the medical team, including Dr Morton. During this time, a number of patients were reviewed.

While on the ward round a patient newly diagnosed with Acute Lymphoblastic Leukaemia (ALL) requested clarification about his treatment regime. The patient, having read the UKALL Trial XII protocol on which his treatment was based, was concerned to know why the protocol stated that the administration of the intrathecal methotrexate and intravenous Vincristine was supposed to take place on the same day, yet his own prescription chart indicated that they would be given on different days.

Dr Gould explained to the patient that it was the QMC policy that the two drugs concerned were administered on different days to prevent them from being mixed up and a fatal accident occurring. Dr Mulhem and Dr Morton were both present on the ward round when the patient was provided with this explanation as to why the protocol had been changed. There are, however, a number of competing views as to what was heard and said at this point but, given the remit of this inquiry, those are issues for resolution by others.

Wednesday 3rd January 2001

Dr Grimley (Staff Grade Doctor) conducted the morning ward round with Dr Mulhem, after which he went to Dr Dolan's (Consultant) clinic. During his time at the clinic, while he did not undertake any medical procedures, Dr Mulhem did see one new patient and reviewed this case with the Consultant. He did, however, also see a number of other follow-up patients on his own.

Sometime during the day, Dr Gould informed Dr Mulhem that he would not be doing much on the ward for the first couple of weeks and that he should "shadow" Dr Grimley, to see how the system on the ward worked. At this point, he was given a plan that showed a timetable for the various clinics that he should attend.

Dr Grimley recalls taking a copy of the 'Haematology Guidelines and Protocols' out of the ward folder and telling Dr Mulhem that he should make a duplicate of it for his own use. Dr Gould recalls asking Dr Grimley if she had provided Dr Mulhem with the guidelines and being informed that she had.

Dr Mulhem, however, says that he never received a copy of the guidelines but remembered asking Dr Sidra, a more experienced SpR, about them. Dr Mulhem then recollected Dr Sidra looking for the guidelines and when he could not find them saying that there was a new version and he would try to find them for him.

At this time, however, there was no formal method for recording whether or not a new SHO or SpR had in fact received a copy of the wards protocols and procedures after they arrived on Ward E17.

Thursday 4th January 2001

Ward E17

Ms Catherine Shanahan (Day Case Co-ordinator) started work at 07.00hrs. She checked the diary and found that Mr Jowett was one of three patients who had not received their chemotherapy over the Christmas and New Year period. It was, however, written in Mr Jowett's notes that he was due to receive his chemotherapy on 4.1.01. After checking with the other Receptionist, Ms Debbie Gillott, Ms Shanahan and Ms Gillott informed Sister Crouch that Mr Jowett and two other patients would require chemotherapy that day.

It was while assessing the requirements of the Day Case Unit that it was brought to Sister Crouch's attention that there were a number of patients who, although they had been booked to receive chemotherapy, it had been delayed due to the Christmas and New Year Period. As a result, these patients had not had their chemotherapy ordered. Sister Crouch then arranged for Dr Musuka to write out their prescription charts, including Mr Jowett's as he was one of these patients, and, using the hospital air tube system, the prescription charts were sent to the SPU to be made up.

Mr Jowett's prescription

Dr Musuka entered the two drugs that Mr Jowett was to receive into the 'Regular Prescription' section of his chart (Appendix 7). The drug Vincristine, although to be administered chronologically second, was written sequentially first as item 'C', dose 2mg, route IV, date to be administered "5.1.1". The drug Cytosine was entered beneath as item 'D', dose 50mg, route changed from IV to IT and highlighted with a second bracketed (IT) to mark the change, date to be administered "4/1/01".

Ward E17

At around 11.30hrs Sister Crouch and others on the Day Case Unit realised that Mr Jowett had not arrived for his appointment. This, however, was not unusual. Dr Musuka having assessed Mr Jowett's medical notes said that he wanted to see Mr Jowett when he arrived. Apparently, this comment was made in front of a group of staff but not directed at any one in particular and it was not entered into the patient's medical notes.

Sterile Production Unit

Jeff Graham, the Pharmacist for Ward E17, had not been notified on his ward round of the additional patients for chemotherapy. On his return to the SPU, he found the prescription charts on his desk. A colleague informed him that someone had rung down from Ward E17 about patients requiring unplanned chemotherapy. Because of the telephone call, Mr Graham was under the impression that the patients were either on the ward or would be very soon. As a result, he believed that the Cytosine for Mr Jowett was urgently required so he made a verbal request that it should be made up straight away and that the Vincristine should be sent afterwards.

When looking at the prescription chart, Mr Graham observed that Mr Jowett's injection of Vincristine was due for the following day so he noted in the SPU log that it would be required "Fri AM" and "SEND SEPARATELY". While Mr Graham had never annotated the production log in such a way before, he was

concerned about the safety implications on this occasion. He did, however, make a verbal request to the ATO, Mr Giles Wilson, that the Vincristine should also be made up so that it would be ready for use on the Friday morning. This, as noted earlier, had become common practice in order to avoid patients having to wait any longer than was necessary on their visit to Ward E17 for chemotherapy.

Because there was no prescription for oral medication, Mr Graham left the prescription chart in the SPU so that it could be returned to Ward E17 with Mr Jowett's intrathecal injection of Cytosine.

Once the production log had been completed, Mr Wilson transcribed the details of Mr Jowett's chemotherapy to his individual Cytotoxic Worksheet. He then checked the details on the Cytotoxic Worksheet against Mr Jowett's profile, which described the exact chemotherapy protocol that he was following. A Senior Technician then checked the formula worked out by Mr Wilson, after which Mr Jowett's Cytosine was made in the SPU. After the Cytosine was produced, a pre-filled syringe of Vincristine was acquired. The drugs were then checked by a Pharmacist, Ms Patricia Dutheil, after which, each of the labelled syringes containing Mr Jowett's chemotherapy were packed in to separate clear plastic mini-grip bags.

Some time later, the Pharmacy had another phone call from Ward E17 asking for Mr Jowett's chemotherapy. Although Mr Wilson knew of the general rule of not sending Cytosine and Vincristine to the ward together he did not challenge the request or seek advice before doing so. It should be remembered at this point that the Pharmacy did not have a mandatory written policy to ensure that the rule was always obeyed and that it was custom and practice to comply with requests made by ward staff.

On reaching the dispensary, Mr Wilson placed the two drugs comprising Mr Jowett's chemotherapy in the refrigerator on separate shelves and put the prescription chart together with the Cytosine that was to be administered to him that day. He then filled in the 'Collection of Specials and Chemotherapy from the Dispensary by Ward Staff' sheet as required before leaving.

Thursday afternoon

Dr Mulhem attended the morning ward round carried out by Dr Grimley after which he supervised Dr Wendy Lawson, an SHO doing two bone marrow biopsies. Following this he went to a lunchtime meeting chaired by Dr Gould.

At the lunchtime meeting that Dr Gould chaired she introduced Dr Mulhem to all the members of staff present, who included: Dr Morton, Sister Crouch, Dr Musuka and Dr Grimley. Dr Gould told all those present that Dr Mulhem would be shadowing Dr Grimley and explained that he would have no direct responsibility for the next two weeks.

Dr Musuka recalls Dr Gould telling the staff present that Dr Mulhem would have to familiarise himself with the ward protocols and procedures and that he should shadow Dr Grimley.

Sister Crouch also remembers Dr Mulhem being told by Dr Gould that he should shadow Dr Grimley. However, while Sister Crouch is aware of what this would mean in a nursing context, i.e. the person concerned would be working with someone senior to them and have a supernumerary position, she was not sure what shadowing was intended to mean in terms of the medical staff. In the event, Sister Crouch did not relay the fact that Dr Mulhem was to shadow Doctor Grimley to her staff.

Similar to Sister Crouch, Dr Morton notes, "The precise meaning of 'shadowing' was not explained to me." Thus, whilst Dr Morton was aware that Dr Mulhem would be shadowing Dr Grimley, he did not appreciate that the term was intended to convey that there were restrictions on Dr Mulhem's clinical activities.

In fact, Dr Grimley did not assume that Dr Mulhem would be doing nothing. Generally speaking, it would appear that when a doctor shadows another it is not intended that they should do no clinical work at all, but rather they must only undertake those activities that they feel competent to perform.

Dr Grimley was not at work on Thursday afternoon as she only works part-time. So, during the course of the afternoon, Dr Mulhem carried out a couple of bone marrow biopsies and dealt with a number of clinical problems on the ward.

Historically, Thursday afternoons on Ward E17 were not very busy. As a result, although Dr Myers who had been rostered for that afternoon was on holiday it was decided not to nominate another SpR for duty. The Duty Consultant and an SHO could always cover any work that might arise. However, if a patient's chemotherapy had been planned for that Thursday afternoon, then Dr Grimley would have stayed on duty. Thus, on Thursday 4th January 2001, when there were no patients scheduled for chemotherapy in the afternoon, Dr Grimley went home following the lunchtime meeting, leaving Dr Musuka as the Duty Consultant and Dr Morton as SHO to cover the ward.

However, Dr Mulhem also happened to be on the ward that Thursday afternoon, undertaking biopsies, attending to clinical problems on the ward, reading patient notes and generally preparing himself for his new position. Also, as a member of staff, Dr Mulhem wore a badge quite clearly identifying him as a SpR.

Collection of Mr Jowett's chemotherapy

Sometime during the afternoon, Ms Shanahan received a telephone call to say that Mr Jowett's chemotherapy was ready for collection. She went to 'B' Floor Pharmacy where she was given a clear bag containing two syringes. (A reconstruction of the bag can be seen in Plate 5). Each syringe had been labelled and packed in separate clear mini grip bags. In one clear mini grip bag was a syringe containing Vincristine to be administered intravenously. While the other clear mini grip bag contained a syringe containing Cytosine for intrathecal administration.

Having checked the patient's name was correct she signed for the drugs; the time of day is not recorded. She then took the chemotherapy and the prescription chart back to the ward. Ms Shanahan did not however inform Staff Nurse Vallance that Mr Jowett's chemotherapy had been collected and placed in the Day Case Unit refrigerator.

What Ms Shanahan and the person who dispensed the chemotherapy to her did not know however was that the two types of drugs should not be in the same place together and never in the same bag.

It is, however, not clear to the panel why Mr Jowett's chemotherapy was collected before he arrived on the ward, particularly as he had missed his morning appointment and had not given any prior notice that he would be attending that afternoon, except to note that chemotherapy was typically collected from the Pharmacy whenever the ward was notified that it was ready.

Since there is no record of who dispensed the drugs to Ms Shanahan and she cannot remember, it has also not proved possible for the inquiry panel to determine exactly why both types of chemotherapy came to be in the same bag. But as noted earlier, where several items of chemotherapy had been prescribed for a patient, it was accepted practice for the items to be dispensed in one common bag.

Admission to Ward E17

Mr Jowett arrived unannounced on the Day Case Unit with his grandmother sometime between 15.30hrs – 15.45hrs. At approximately 16.00hrs, Staff Nurse Vallance took a blood sample from Mr Jowett. Having done so, she informed Dr Morton that Mr Jowett was in the Day Case Unit. Staff Nurse Vallance then pointed out that, because the treatment required an intrathecal injection an SpR had to be present.

Ms Shanahan went off duty at 16.00hrs, not having informed Dr Musuka that Mr Jowett had arrived at the Day Case Unit. Although Sister Crouch spoke to Mr Jowett as she was going off duty at about 16.30hrs she did not think to inform Dr Musuka that he had arrived.

Proceedings leading to the adverse incident

Just before 17.00hrs, Dr Mulhem was approached by Dr Morton in the Doctors' room (Appendix 3) and informed that a patient, Mr Jowett, was due to have an intrathecal injection of chemotherapy. Up to this point, Dr Mulhem had not been involved in the administration of any chemotherapy on Ward E17. However, because he knew that Dr Morton had been at QMC for a few months, he assumed that Dr Morton knew the patient and understood what was to take place by way of treatment.

As a result, Dr Mulhem also assumed that it was not necessary for him to go back through the patient's notes to check the various treatment protocols, and that his supervision of Dr Morton was simply a basic overview of another doctor who was familiar with the patient's condition and treatment.

In fact, Dr Morton, as noted earlier, had only been on the ward for five weeks, did not know Mr Jowett and was also not aware of the danger that the intrathecal administration of Vincristine posed to patients. In any event, Dr Mulhem agreed to supervise Dr Morton.

At this point Dr Mulhem went to the Treatment Room (Appendix 3) and Dr Morton went to check the patient's blood count.

At about 16.50hrs Dr Morton arrived at the Day Case Reception, where Staff Nurse Vallance was in the process of looking up Mr Jowett's blood count on a computer. Staff Nurse Vallance read the results of the blood count, which were satisfactory, to Dr Morton who wrote them straight into Mr Jowett's clinical notes. Dr Morton then introduced himself to Mr Jowett and his grandmother and took Mr Jowett to side room six, which had been allocated for his treatment and the rest period he would require after the procedure had been completed.

When Dr Morton returned to the Treatment Room, Dr Mulhem was preparing a lumbar puncture kit and the treatment trolley. When it had been established that Mr Jowett's blood count was satisfactory, Dr Mulhem told Dr Morton that they would "go ahead" with Mr Jowett's chemotherapy.

When Staff Nurse Vallance entered the Treatment Room, both Dr Morton and Dr Mulhem were present and asked if she knew where Mr Jowett's chemotherapy was. As Staff Nurse Vallance could not see any chemotherapy in the refrigerator in the Treatment Room, and wanting to be of help, she went to look in the refrigerator in the Day Case Unit (Appendix 3).

At around this time Dr Morton left the Treatment Room and went to get the spinal needle that he needed to carry out the lumbar puncture.

Having opened the Day Case Unit refrigerator Staff Nurse Vallance removed the only item of chemotherapy in the refrigerator. It was the transparent plastic bag, placed there by the Day Case Co-coordinator, within which were two separate transparent packets each one containing a syringe. She noted that the name 'Wayne Jowett' was printed on each of the syringe labels by reading through the outer transparent package. Staff Nurse Vallance then took this package to the Treatment Room, where only Dr Mulhem remained. He was putting equipment in a blue tray. She recalls saying, "Here's Wayne's chemo" and Dr Mulhem took the packet from her hand.

Staff Nurse Vallance then asked Dr Mulhem if she could be of any further assistance. Dr Mulhem asked her for a number of other items which he needed to carry out the procedure. Having got the items required by Dr Mulhem Staff Nurse Vallance then left the room to carry on with her work.

It should be remembered at this point that, because the intrathecal administration of chemotherapy is the sole preserve of the medical staff, the nursing staff on Ward E17 perceived the procedure as having nothing to do with them. Staff Nurse Vallance was not asked to assist at the procedure. Nor did she see Mr Jowett's chemotherapy prescription chart, nor was she asked to carry out any checks. Furthermore, since a doctor always delivers intrathecal treatment, it is not normal practice for the nursing staff to set up a trolley for the procedure unless they are specifically requested to do so.

Dr Mulhem had a brief look at the prescription chart noting that the patient's name, drugs and dosages corresponded with the information on the labels attached to the syringes. He did not, however, notice that the administration of the Vincristine was planned for the following day or that its route of administration was intravenous.

Dr Mulhem, anticipating a cytotoxic drugs system similar to the one at LRI would be in place at QMC, had fixed in his mind that, as both drugs had come up to the ward together, both were planned for intrathecal use. It should be noted that, while working at LRI, Dr Mulhem had on a number of occasions administered two drugs to patients during an intrathecal procedure. Thus, Dr Mulhem did not consider the fact that there were two lots of chemotherapy to be administered intrathecally required any investigation.

Having got a spinal needle, Dr Morton went to side room six where Mr Jowett was waiting for treatment. Upon entering the side room, he noticed that Dr Mulhem had set up a treatment trolley and that he had prepared the patient for the lumbar puncture. Landmarks were identified and the L4 joint space was marked with a small indentation of the thumb.

At this point Dr Morton washed his hands and put on sterile gloves and administered a local anaesthetic under Mr Jowett's skin.

Dr Morton has stated that the "...patient was quite anxious so 2 minutes were allowed for good analgesic effect. I recall Dr Mulhem asking me if I was happy to give the treatment and I replied in the affirmative."

The next thing that Dr Morton did was to explain the lumbar puncture process to Mr Jowett, after which he commenced the procedure. Dr Mulhem watched while Dr Morton carried out the lumbar puncture, advising him on the positioning of the patient. When the lumbar puncture had been carried out successfully, samples of cerebro spinal fluid were taken for analysis

At this point Dr Mulhem read out aloud the name of the patient, the drug and the dose from the label on the first syringe and then handed it to Dr Morton. Dr Mulhem did not, however, read out the route of administration.

Dr Morton, having received the syringe, now asked if the drug was "Cytosine" to which Dr Mulhem replied in the affirmative. Dr Morton then removed the cap at the bottom of the syringe and screwed it onto the spinal needle after which he injected the contents of the syringe. Once the injection was complete, Dr Morton unscrewed the syringe and handed it back to Dr Mulhem.

At this time Dr Morton was kneeling on the floor in order to carry out the procedure and Dr Mulhem was standing looking over Dr Morton's left shoulder. A reconstruction of an intrathecal procedure can be seen in Plate 6. However, the position of the two doctors is different because in the photograph the procedure is being conducted from the left hand side of the bed, whereas Dr Morton and Dr Mulhem were on the right hand side of the bed.

Having put the first syringe down, Dr Mulhem handed the second syringe containing Vincristine to Dr Morton, again reading out aloud the name of the patient, the drug and dosage to be administered. Once again, he did not read out the route of administration. However, Dr Mulhem cannot now recall if he:

"...actually said the word 'Vincristine' but once again I had clearly fixed in my mind that the drug was Methotrexate and not a drug for administration other than IT. If I had consciously appreciated that the drug

was Vincristine I would have stopped the procedure immediately and would never allowed Dr Morton to administer it.”

Dr Mulhem cannot explain the fact that he translated the word “Vincristine” for “Methotrexate”, except for the fact that his mindset was that drugs for administration by a route other than intrathecal would simply not be available at the same time. However, it should be noted that oral Methotrexate had been prescribed for Mr Jowett and was one of the drugs written in block capitals in the “Treatment Regime” section on the front of Mr Jowett’s prescription chart (Appendix 8).

Dr Morton was surprised when he was passed a second syringe, because on the only other occasion that he had performed a supervised intrathecal injection only one syringe had been used. However, he assumed that on this occasion that “...the patient was either at a different stage in his treatment or was on a different treatment regime than the other patient.”

Dr Morton now having the second syringe in his hand “...said to Dr Mulhem “Vincristine?” Dr Mulhem replied in the affirmative. Dr Morton then said “intrathecal Vincristine?” Dr Mulhem again replied in the affirmative. After which Dr Morton removed the cap at the bottom of the syringe and screwed it onto the spinal needle. He then administered the contents of the syringe to Mr Jowett.

After the cytotoxic drugs had been administered to Mr Jowett, a dressing was applied to the wound made by the spinal needle and he was told to lie flat for 2 hours. He was also informed that if he suffered a headache to drink plenty of water. Dr Mulhem then pushed the trolley to the Treatment Room in order to dispose of the syringes and other used items.

During the administration of Mr Jowett’s chemotherapy, there was some dialogue between Dr Mulhem and Dr Morton. There is, however, a difference of opinion as to what exactly was said by each person. Dr Mulhem cannot recall a query being raised with him by Dr Morton about the Vincristine. But says that he would have told him to proceed in any case, believing in his own mind that it was correct to do so.

As to why Dr Morton did not challenge Dr Mulhem regarding the decision to administer the Vincristine intrathecally, if he thought something was wrong, Dr Morton states:

“First of all, I was not in a position to challenge on the basis of my limited experience of this type of treatment. Second, I was an SHO and did what I was told to do by the Registrar. He was supervising me and I assumed he had the knowledge to know what was being done. Dr Mulhem was employed as a Registrar by QMC which is a centre for excellence and I did not intend to challenge him.”

At approximately 17.15hrs, Staff Nurse Vallance went into the Treatment Room where Dr Morton appeared to be querying some detail on Mr Jowett’s prescription chart. At this point Dr Morton, Dr Mulhem and Staff Nurse Vallance once again have slightly different recollections as to what took place. However, for the purpose of this inquiry, it is sufficient to note that it was at this time when it was realised that a grave mistake had been made.

Dr Mulhem did not know what the likely consequences of intrathecal administration of Vincristine would be at this stage, but was concerned to notify a Consultant immediately. He contacted Dr Musuka who came straight away.

Dr Musuka then contacted Dr Gould and informed her of what had occurred. Other members of the medical and nursing team who were not aware of Mr Jowett’s condition were then informed and urgent remedial treatment commenced.

Chapter 4: Analysis

Tacit assumptions

The evidence presented to this inquiry suggests that the people who belonged to the various groups of QMC staff which were involved in some way with the provision of Mr Jowett's treatment held a number of tacit assumptions regarding that process. Prior to the accident, these taken for granted perspectives appear to have been firmly held and acted upon. The evidence also suggests that all those involved considered that they were acting at all times in the best interests of the patient. The list of assumptions below is not intended to be exhaustive but indicative of the beliefs that appear to have made a contribution to the adverse event that took place.

The medical team involved in the adverse incident

Dr Mulhem appears to have assumed that:

- Chemotherapy for different routes of administration could not be on the ward at the same time for the same patient.
- He was competent to supervise Dr Morton and had the authority to do so.
- Dr Morton was allowed to administer intrathecal drugs under supervision of an SpR.
- Dr Morton was familiar with Mr Jowett's case and, treatment regime, and thus he did not need to consult Mr Jowett's records.
- He knew the correct procedure to adopt when checking intrathecal drugs for administration.
- Both syringes of chemotherapy were to be administered intrathecally.

Dr Morton appears to have assumed that:

- He was allowed to administer intrathecal chemotherapy to patients under supervision.
- Dr Mulhem was authorised to supervise him administer intrathecal chemotherapy.
- As an SpR Dr Mulhem would know about drugs for intrathecal administration and the dangers associated with them.
- Dr Mulhem would know what checks to carry out regarding the administration of intrathecal drugs.
- He should not challenge a senior colleague.

Examination of assumptions

From the assumptions, noted above, it can be observed that both Dr Mulhem and Dr Morton held a number of beliefs regarding the situational context of the procedure that they were about to perform, which were inaccurate. However, Van Maanen (1977:20) has observed:

“A newcomer assumes that he knows what the organization is about, assumes others in the setting have the same idea, and practically never bothers to check out these assumptions.”

Thus, without any explicit guidance as to what clinical activities they could or should not perform, neither of them had any way of knowing that they were about to contravene Ward E17 protocols. And although Dr Mulhem had been instructed to “shadow” his mentor Dr Grimley, from his actions it is clear that he had not understood the nature of the restrictions that were now supposed to limit his clinical activities. The senior medical staff on Ward E17 had not explicitly defined the term “shadowing” and, therefore, it was left open to Dr Mulhem’s interpretation.

With respect to Dr Mulhem checking the drugs prior to administration, as noted earlier, he had not received any ward or QMC guidelines or protocols to which he could refer. Even if he had read the Ward E17 guidelines, there was no explicit systematic protocol regarding the checking of chemotherapy or its administration to which he could have referred. Thus, given that Dr Mulhem had no formal training in cytotoxic chemotherapy at LRI or QMC, he could only call upon the practical experience that he had gained at LRI. In the event, his past experience was not sufficient and a series of errors were made.

A similar scenario can be envisaged when Dr Mulhem decided which of the details on the labels he would check with Dr Morton as he passed him the syringes of chemotherapy. Believing that it was impossible for a drug to be present which was not for intrathecal administration, he sanitised the world of hazards (Smith and Toft, 2001) and in doing so passed Dr Morton the syringe containing Vincristine. It should also be remembered at this point that in, the copy of the Ward E17 guidelines that Dr Morton had been given, the line of text warning not to give Vincristine on the same day as an intrathecal drug was missing. So, he could not have known about the danger posed by Vincristine from that source of information.

Compounding Dr Mulhem and Dr Morton’s inaccurate assumptions are a number of other factors. These are presented in the following sections. First of these is the fact that Thursday afternoons were usually quiet and as a result, a duty Registrar had not been nominated, as would be the case on any other weekday afternoon. In addition, as no chemotherapy had been planned for that afternoon and Mr Jowett had not informed the ward that he was now going to attend, Dr Grimley had gone home following the lunchtime meeting.

Therefore, the circumstances when Mr Jowett arrived on Ward E17 that afternoon were quite unusual. Instead of there being just a SHO to cover the ward, i.e. Dr Morton, there was what appeared to be a qualified SpR working there as well. Thus, if Dr Mulhem had not been present, Dr Morton would have had to call Dr Musuka to administer Mr Jowett’s chemotherapy. Similarly, on any other weekday afternoon, one of the Registrars would have been nominated to cover work on the ward and he or she would have supervised the administration of Mr Jowett’s chemotherapy. However, as Dr Mulhem was on Ward E17 that Thursday afternoon, it was he who was approached to supervise the procedure.

Another factor is that both drugs were prescribed on the same prescription chart. Thus, the prescription chart did not immediately present the medical team with a visual cue, i.e. in a number of hospitals intrathecal chemotherapy is prescribed on a separate prescription chart, using a different colour, to drugs administered intravenously.

If such a system had been in place on Ward E17, the likelihood of an adverse event occurring could have been reduced. In the first instance, a different coloured prescription chart would, like the use of the yellow box at LRI, have flagged to the physicians concerned that particular care was required. Secondly, the Vincristine would not

have been entered on to the prescription chart and thus Dr Mulhem would have had a drug present that had not been prescribed. Thus clearly signalling that something was wrong.

As noted earlier, the labelling was almost identical for the two types of drugs save for the difference in routes of administration. In addition, the name of the drug, dose and its volume was the information highlighted by bold type. There was no visible cue, such as different coloured print on the labels of the drugs, to help flag up that there was a different type of drug in each package.

In a similar way, the packaging of the two drugs was identical apart from the words on the labels affixed to them. Thus, the packaging did not provide a visible cue to alert staff that drugs that had to be administered by entirely different routes were present in the two packets.

The syringes were of a similar size and the volume of drugs to be administered was only slightly dissimilar. The protective caps on this occasion, grey on the syringe containing the Vincristine and red on the syringe containing the Cytosine, were different. However, if the dose of Vincristine given to the patient had been smaller, the correct dose would have been drawn from the pre-filled syringe into an SPU syringe and a red cap fitted. Thus, the colour of the protective caps is not a visible cue that a physician could rely on at the present time, as the colour coding of the cap on a syringe is not consistent. As noted above, a pre-filled syringe containing Vincristine does have the drug's name and a warning that it should not be administered intrathecally on the side in blue letters. However, the size of type is small and the label that had been put on in the SPU obscured a portion of the total printed text, thus de-emphasising the importance of the message.

Clearly, if the volume of Vincristine had been significantly greater than the Cytosine, this would have provided the medical team with a visual prompt to examine the drug and the information provided far more closely. However, the idea of diluting Vincristine had never been considered by the Pharmacy.

As discussed earlier the only drug administered intrathecally whose colour provides a visual cue (yellow) is Methotrexate. It is difficult, therefore, to understand how Dr Mulhem could have confused it with Vincristine, a drug that has no colour. Except for the fact that his mind-set had discounted the possibility of it being present. And, as I pointed out earlier, I note that the word "METHOTREXATE" (Appendix 8) was also present in the "Treatment Regime" section on the front of Mr Jowett's prescription chart.

Another factor was that the syringe, which contained Vincristine, could also be attached to the spinal needle used in the intrathecal procedure. Thus, as there was no indication that anything was amiss, Dr Morton attached the syringe containing Vincristine to the spinal needle and administered the drug to Mr Jowett. However, if it had been impossible for the syringe to be connected to the spinal needle, then it is difficult to see how this adverse event could have taken place.

Finally, although Dr Morton felt unease at administering the Vincristine, he did not feel that he could challenge Dr Mulhem because he did not understand enough about the procedure or the patient's treatment regime.

Dr Mulhem and Dr Morton both appear to have experienced the newcomer syndrome described by Van Maanen above. They failed to recognise that their taken-for-granted assumptions about the working environment, themselves and each other were at variance with reality. The gap between their subjective perceptions of the situation and objective reality led to errors of judgement being made and subsequently to the death of Mr Jowett.

Senior Medical Personnel Ward E17

Collectively Dr Gould, Dr Musuka and Dr Grimley appear to have assumed that:

- Because the UKALL Trial XII protocol had been changed, drugs to be administered by different routes could not be on Ward E17 at same time for the same patient.
- Dr Mulhem knew about cytotoxic chemotherapy and the danger of Vincristine.
- There was no need for a formal induction course for SHOs and SpRs.
- Dr Mulhem understood what ‘Mentoring’ and ‘Shadowing’ meant, i.e. he was not to administer chemotherapy to patients while on this induction period unless supervised by at least a Staff Grade Doctor.
- Dr Morton, the SHO, would not administer chemotherapy to patients unless supervised by one of them.
- The current training regime for SHOs and SpRs was satisfactory.
- Ward E17 “Haematology Guidelines and Protocols” were satisfactory and so was the method of delivery to new SHOs and SpRs.
- The ‘Open Door’ policy implemented for SHOs and SpRs worked satisfactorily and any problems would be raised before patient safety was compromised.
- The Haematological Unit was safely run and everyone adhered to the protocols and procedures laid down at all times.

Examination of assumptions

The UKALL Trial XII protocol had been changed to ensure that drugs intended for administration by different routes could not be on the ward at the same time for the same patient. Thus, there was no reason for the wards senior medical personnel to suppose that such an event could now take place.

Furthermore, given that Dr Mulhem had been working in the Haematology Department at LRI for almost a year and was a well-respected SHO, it is easy to see how it could be thought that he would be familiar with all of the procedures regarding the administration of chemotherapy and the danger associated with Vincristine. Similarly, the assumption was made that Dr Mulhem understood what was intended when instructed to shadow Dr Grimley, for he did not raise any questions regarding what was required of him. However, neither Dr Gould nor Dr Grimley questioned Dr Mulhem to ensure that he did understand what was intended.

Prior to Mr Jowett’s death, there was no evidence presented to suggest that there had been any serious problems on Ward E17. Thus, the assumption that their policy on training, explicit guidelines, protocols and the system for providing them were satisfactory is understandable. Also, the lack of any serious problems would also support the senior medical personnel’s belief that their “Open Door” policy was working and that as a consequence a formal induction course was not required. Therefore, their conviction that the department was running smoothly and safely was supported by their everyday work experiences.

However, just as with Dr Mulhem and Dr Morton, there were differences between the senior medical personnel’s perceptions and objective reality. Unknown to them the change, which they had made to make the UKALL Trial XII protocol safer was being unwittingly overridden by the nursing and Pharmacy staff. The rationale behind this

action was to save patients the inconvenience and stress of having to wait for their chemotherapy once they had arrived on the ward. However, this unsanctioned informal practice led, as discussed earlier, to drugs for both routes of administration being on Ward E17 at the same time and for the same patient.

Thus, their assumption that all ward protocols and guidelines were being adhered to was mistaken. In a similar vein, they were also not aware that neither Dr Mulhem nor Dr Morton knew of the danger that Vincristine posed. They also did not realise that the different sources of information on the ward that would normally be brought to the attention of new medical staff failed to explicitly spell out that danger.

Hence, insofar as Dr Mulhem and Dr Morton appear to have been subject to Van Maanen's 'newcomers' assumptions, it would also seem the senior medical personnel were victim of what might be loosely termed 'veterans' assumptions, i.e. they assumed that the mental models which they possessed were the same or similar to those who joined them. Unfortunately, that was not the case. Thus, there was a gap between what the senior medical personnel perceived to be the case and what was actually taking place. This unseen disparity between perception and reality formed part of the internal organisational setting that led to Mr Jowett's death.

Dr Musuka also appears to have assumed that:

- If Mr Jowett attended the Day Case Unit, he would be called because he had left a verbal instruction to that effect.

Examination of assumption

It is reasonable to assume that, when a verbal instruction is left, to be called when a particular patient arrives, that this is what will happen. However, it is easy for people to forget any instruction if it is not written down to remind them. Thus, since Dr Musuka's instruction was not written into Mr Jowett's medical notes or the ward diary there was nothing to remind the staff to call him. Consequently, he was not alerted that Mr Jowett had arrived on the ward. Which again was one of the links in the chains of events that led up to the adverse event taking place.

Nursing Staff Ward E17

Sister Crouch and Staff Nurse Vallance appear to have assumed that:

- There was no danger in allowing staff that do not have special training in chemotherapy to collect drugs from 'B' Floor Pharmacy.
- There was no danger to patients in storing drugs on the ward with different routes of administration because all the necessary checks will always be made.
- There was no need to make arrangements to have drugs with different routes of administration kept separated when they are on the ward because all the necessary checks will be made.

Examination of assumptions

One of Sister Crouch's main priorities was for the ease of comfort of her patients. She was concerned over the time it took on some occasions to get their chemotherapy from the SPU. Thus, she made every effort to arrange for chemotherapy to be available to patients as soon as they arrived.

As noted above, the checks that nurses carry out with regard to the administration of intravenous chemotherapy are very rigorous and designed to reduce human error to as low a risk as possible. Therefore, providing the

protocol is followed on each occasion that chemotherapy is administered, the risk is very small that a drug will be inadvertently administered by the wrong route.

Thus, it was crucial that everyone having any contact with cytotoxic chemotherapy knew that the two types of drugs must be kept apart at all costs. However, the Day Case Co-ordinator was allowed, without training, to collect chemotherapy. Thus, having no knowledge of cytotoxic drugs, the Day Case Co-ordinator did not realise that the chemotherapy for which she signed on that Thursday afternoon should never have been released together. Or that she should inform the Ward Manager or the Staff Nurse that such drugs were now on the ward.

The practice of not allocating separate areas for the intravenous and intrathecal drugs in the ward refrigerators would also appear to have been predicated on the fact that the two types of drugs for a patient would come on to the ward on different days, in which case it did not matter. Or if they did come on to the ward together, they would be thoroughly checked as they were removed from the refrigerator as demanded by the protocol.

In the situation that developed, the safety of patients depended upon everyone using a rigorous checking protocol to ensure that they administered the chemotherapy by the correct route and while the nurses had an explicit protocol to follow, the medical staff did not. This is where there was a divergence between Sister Crouch and Staff Nurse Vallance's perception of the situation and reality. They clearly assumed that everyone that administered chemotherapy would use a rigorous procedure.

Staff Nurse Vallance appears to have assumed that:

- Dr Morton was the duty SHO and so should be informed that Mr Jowett had arrived.
- The new SpR was to do the procedure.
- Doctors carried out intrathecal injections and they would do all the necessary checks.

Examination of assumptions

Staff Nurse Vallance had seen Dr Mulhem working on Ward E17 and Dr Morton was the duty SHO. Without any information to the contrary, she assumed that they would undertake Mr Jowett's treatment.

As they were both experienced doctors, Staff Nurse Vallance also assumed that they would know of the dangers of Vincristine, particularly as the administration of intrathecal drugs is only ever undertaken by the medical staff. Also, given that it was common practice for doctors to obtain any chemotherapy that they required for patients, Staff Nurse Vallance assumed that they would carry out all the appropriate checks before commencing the procedure.

Therefore, since Dr Mulhem and Dr Morton had made an informal request to Staff Nurse Vallance to fetch Mr Jowett's chemotherapy and they had not given her Mr Jowett's prescription chart, Staff Nurse Vallance believed that it was not necessary for her to carry out any checks after removing Mr Jowett's chemotherapy from the Day Case refrigerator. Similarly, on her return to the Treatment Room Dr Mulhem took the chemotherapy from her but did not ask her to carry out any checks, so she assumed that he and Dr Morton would do so. Thus, there was a mismatch between Staff Nurse Vallance's perception and reality, and that difference, in hindsight, proved to be another link in the chain of unseen events that led to the adverse incident.

Pharmacy Staff

Jeannette Kendall Assistant Chief Pharmacist appears to have assumed that:

- It was acceptable to send drugs with different routes of administration to the ward at the same time when requested by the ward nursing staff.

- There was no need to have a written policy on dispensing drugs for intrathecal administration.
- The labelling system was satisfactory.
- The packaging system was satisfactory.
- The syringes used for the administration of intrathecal and intravenous drugs were satisfactory.
- It was not necessary to have staff specifically trained in cytotoxic drugs appointed to dispense chemotherapy from 'B' Floor Pharmacy or to have the person who dispenses such drugs identified by their signature.

Examination of assumptions

In her evidence Ms Kendall when asked, "How often does a request come for both drugs to be sent together?" replied "A lot". And the reason why intrathecal and intravenous drugs were sent to the ward together was because they "did not want the pharmacy to be accused of compromising patient care".

It should be remembered that the UKALL Trial XII protocol (May 1995: 18), which the Pharmacy works to, actually states that the drug Cytosine should be administered "...every three months at the same time as the Vincristine." Although, because they were aware of the danger of Vincristine being accidentally administered intrathecally, the instruction was that drugs should be sent to the ward on different days or at different times.

Thus, presumably because intrathecal and intravenous drugs were frequently sent together it could have been thought that there would be no point having a written policy regarding the dispensing of intrathecal and intravenous drugs together as it would be continually overridden.

As there appears to have been no problems or complaints about the labelling or packaging of intrathecal and intravenous drugs, both systems were deemed to be satisfactory. Similarly, it was also thought that the drug delivery system, i.e. the syringes that were used, did not pose any problems.

If intravenous and intrathecal drugs are going to end up on the ward together it may have seemed pointless to have someone specially trained in cytotoxic drugs to make sure they stay separate in the dispensary.

However, because the person who dispensed the chemotherapy was not required to sign to that effect, a break has occurred in the audit trail. This has denied the inquiry panel vital evidence of exactly how the two drugs came to be together in the same bag. Although, as noted earlier, it would in fact appear that it was normal practice where there were a number of items of chemotherapy for one patient, for them to be dispensed within one outer bag.

Mr Wilson Pharmacy Assistant Technical Officer appears to have assumed that:

- It was acceptable to send drugs with different routes of administration to Ward E17 at the same time when requested even when there is an instruction not to.
- Ward E17 would operate a safe system and they knew what they were doing.

Examination of assumptions

Given the Pharmacy's policy of not wishing to compromise patient care and thus always responding to requests to send intrathecal and intravenous drugs together, it would seem that Mr Wilson's assumption was appropriate.

Similarly, when asked a question about how did he think the intrathecal and intravenous drugs would remain separate once they had been collected from 'B' Floor Pharmacy, Mr Wilson stated that he thought the "Ward

staff should know”. Which, of course, is appropriate as the nursing staff on Ward E17 on Thursday 4th January 2001 did know that such drugs should be kept separate. Hence, his perception of his working environment and reality appears to have been congruent.

Mr Graham Ward E17 Pharmacist appears to have assumed that:

- If he left an instruction on the Cytotoxic Log sheet that the Vincristine for a patient was to be sent to Ward E17 on Friday morning that this was what would have occurred and that it would have been sent on the day stated.

Examination of assumption

While it is reasonable to assume that an explicit instruction will be followed, given the Pharmacy policy on supplying cytotoxic drugs to the ward it is perhaps not surprising that the request by Ward E17 took precedence.

Day Case Coordinator

Ms Shanahan appears to have assumed that:

- The medical and nursing staff all knew what they were doing and there was nothing to be concerned about.
- If she was required to have known some thing, they would have told her.

Examination of assumption

Ms Shanahan had collected cytotoxic drugs from ‘B’ Floor Pharmacy for quite some time thus it was reasonable for her to assume that if she needed to know about the drugs she would have been told.

QMC Drug Custody and Administration Code of Practice

The distribution of the document named above was the responsibility of the Pharmacy. Thus, once the document had been distributed around QMC, there was an assumption that all members of nursing and medical staff would know of the document’s existence. However, it would appear that the document was predominately directed towards the nurses as opposed to the medical staff. The Clinical Director of Medicine at QMC had not seen a copy of this document and neither had the medical staff on Ward E17.

The fact that this document was not drawn to the attention of the medical staff on Ward E17 is unfortunate, because it contains a wealth of information. There are numerous topics, including a rigorous systematic protocol for clinical staff to follow when they administer drugs to patients (Appendix 9). It also contains a specific section on the “Prescribing, Dispensing and Administration of Cytotoxic Chemotherapy” (Appendix 10).

Discussion

The evidence presented above demonstrates the complexity of the events that surrounded the death of Mr Jowett. It can be observed that the accident arose through a set of confounding circumstances, which were not explicitly recognised by anyone at the time.

For example, Dr Mulhem and Dr Morton did not realise that, under the circumstances that prevailed in the late afternoon of Thursday 4th January 2001, they did not possess sufficient knowledge or, as it was later determined, the authority to undertake the procedure in the way that they did.

Similarly, the senior medical personnel on Ward E17 did not know that Dr Mulhem was not conversant with the danger of administering Vincristine intrathecally. Furthermore, they were not aware that his chemotherapy administration checking protocol did not include explicitly identifying the route by which a cytotoxic drug was to be administered. Nor did the senior medical personnel responsible for Dr Mulhem's training realise that he had not understood the limits that had been placed on his sphere of clinical activities.

In the same way, the senior medical personnel on the ward did not know that the nursing staff had employed a local work round so as not to inconvenience patients, which nullified their modification to make the UKALL Trial XII protocol safer.

The senior medical personnel were also unaware that there were two versions of the wards "Haematological Guidelines and Protocols" in circulation, and that the version given to Dr Morton did not have the warning about not administering Vincristine on the same day as an intrathecal injection. It was also not realised by the senior medical personnel that the actual danger that Vincristine posed to a patient would not automatically be recognised by someone reading the guidelines.

Similarly, the senior medical personnel seem to have thought that their "Open Door" was unproblematic for new staff to use and that in some way all problems would be explicitly recognised and brought to them for resolution. They also appear to have considered their initial informal training regime for SHOs and SpRs to be satisfactory.

Dr Musuka also thought it was sufficient to issue verbal instructions whereas they should, wherever possible, be written down so that they do not get forgotten.

In terms of being unaware, the nursing staff followed the same pattern as everyone else, in that they did not know the extent of Dr Mulhem's and Dr Morton's lack of knowledge in relation to the administration of cytotoxic drugs, nor what their powers of authority were. It was also thought by the nursing staff that it was not a problem having chemotherapy on the ward with different routes of administration, an informal approach to its storage and having a member of staff transporting such drugs who had no training in such matters.

While it is clear that there was mutual respect between the Consultants, SpRs, SHO and Nurses on Ward E17 for the professionalism that they all apparently displayed on a day to day basis, it should never be assumed that people do not make mistakes or forget to do things. Thus, the apparent successful running of Ward E17 appears to have lulled its entire staff into a false state of security.

In a comparable way those responsible for running the Pharmacy did not realise that the similarity between labels, packaging, syringes and the volume of solution used for intrathecal and intravenous chemotherapy could, under unforgiving circumstances, assist the process whereby a physician perceived that they were administering one drug when in fact it was another.

In a similar way, allowing Vincristine to go to Ward E17 so as not to compromise patient care was thought not to pose a problem. Likewise, not having specially trained staff to deal with the dispensing of cytotoxic drugs was again believed to be unproblematic. As indeed was the practice of dispensing drugs to Ward E17 based on what had been ordered for each patient, rather than dispensing chemotherapy based on the drug route prescribed for different patients, as was the case with the Paediatric Day Case Unit.

It was also not realised at the time that the Pharmacy distribution system had failed to draw the QMC document "Drug Custody and Administration Code of Practice" to the attention of all the Trusts medical staff. This also played a part in creating the setting for the adverse event to take place. For as can be noted in Appendix 9 the protocol in section 10.4.1 provides a detailed procedure for clinical staff to follow, which also includes checking the route and date of administration.

The fact that there was no nominated duty Registrar for that afternoon, because of the typical light work load, also played a part in the complex web of circumstances that led to Dr Mulhem and Dr Morton undertaking Mr Jowett's treatment. Mr Jowett, by not informing Ward E17 that he would be coming to the ward for his chemotherapy in the afternoon, also played a part in this tragic event, for if he had informed the ward Dr Grimley would have stayed on duty and supervised his treatment.

There is also a national dimension to this incident. While the Joint Council for Clinical Oncology has published a report (JCCO, 1994) that makes a number of recommendations, with regard to some of the managerial and procedural aspects of cytotoxic chemotherapy, they are advisory. Thus, it is difficult to say how widely they may have been implemented nationally. Certainly, Dr Mulhem and Dr Morton had not received any formal training in the practical administration of chemotherapy nor had any of the senior medical personnel on Ward E17, as recommended by the report. Therefore, what a physician knows about chemotherapy protocols will depend upon the local practices of the particular hospital or hospitals in which they have worked. Such as, for example, the fact that in some hospitals patients undergoing combined treatments like Mr Jowett, the practice is to administer Vincristine first and intrathecal chemotherapy second. This is the reverse to the practice at QMC.

If, however, there was a compulsory set of national protocols for doctors to use when administering cytotoxic chemotherapy, the risk of Van Maanen's newcomers syndrome to which Dr Mulhem and Dr Morton appear to have succumbed, would be considerably reduced.

Similarly, if there were specific syringes that could only be fitted to intrathecal spinal needles, for example, with a coupling such as that patented by Dr J. Peters (August, 1995), then the risk of inadvertently administering intravenous Vincristine would be significantly reduced.

It is quite clear that everyone concerned with this adverse event believed that the subjective perceptions that they had regarding their working environment were concrete facts. In hindsight, however, these beliefs can be seen to have been misleading.

Chapter 5: Conclusions and Recommendations

Conclusions

The conclusions that I have drawn from the evidence provided are as follows:

The adverse incident

The immediate and direct causes that underlay the adverse event that led to the death of Mr Jowett are as follows:

The patient's intravenous drug (Vincristine) should not have been on Ward E17 when Mr Jowett arrived to have (Cytosine) administered intrathecally.

No check was undertaken by Staff Nurse Vallance to ascertain what the route of administration was for each of the drugs that she retrieved for Dr Mulhem and Dr Morton from the Day Case Unit refrigerator.

Dr Mulhem did not check the dates on which the drugs were to be administered, nor their route of administration, against Mr Jowett's prescription chart.

Dr Mulhem and Dr Morton did not complete the appropriate checks on the chemotherapy that they administered to Mr Jowett.

The design of the syringe containing the fatal dose of Vincristine permitted it to be connected to the spinal needle used to administer the intrathecal chemotherapy to Mr Jowett.

System Failures

The evidence presented to this inquiry suggests that the adverse incident that led to Mr Jowett's death was not caused by one or even several human errors but by a far more complex amalgam of human, organisational, technical and social interactions (Toft and Reynolds, 1997, Turner and Pidgeon, 1997) which are described below.

Safety Culture

Levitt and March (1988: 320) have observed that:

“Routines are based on interpretations of the past more than anticipations of the future. They adapt to experience incrementally in response to feedback about outcomes.”

Therefore, since Ward E17 at QMC had been operating successfully for a number of years the staff would have had no reason to question their behaviour or the procedures that they adopted.

However Miller (1997, p.88), warns that:

“Failure teaches leaders valuable lessons, but good results only reinforce their preconceptions and tether them more firmly to their ‘tried-and-true’ recipes.”

Thus, success can lead to complacency and professional myopia which will eventually effect an organisation’s culture. The importance of any organisation creating and maintaining a robust safety culture is clearly spelled out in Department of Health (2000: 35) where it is suggested, “People may come and go, but an effective safety culture must persist.”

Unfortunately, the safety culture surrounding Ward E17’s patient chemotherapy supply and administration system does not appear to have been all that it should.

Operational practices

Through not wishing to compromise patient care, the Pharmacy, although well aware of the danger that Vincristine poses to patients who are receiving both intrathecal and intravenous chemotherapy, allowed the drugs to be released together at the behest of Ward E17.

Staff untrained in cytotoxic drugs were allowed to dispense chemotherapy from ‘B’ Floor Pharmacy.

Drugs were dispensed to Ward E17 based on what had been ordered for each patient, as opposed to dispensing chemotherapy based on the drug route prescribed for different patients, as was the case with the Paediatric Day Case Unit.

A member of staff untrained in cytotoxic drugs, i.e. the Day Case Co-ordinator on Ward E17, was allowed to collect, transfer and then store chemotherapy in the ward refrigerators.

Through not wishing to inconvenience the patients, the nursing staff on Ward E17 inadvertently negated the change made by the medical staff to the UKALL Trial XII protocol, i.e. intrathecal and intravenous chemotherapy should be brought on to the ward on separate days.

There was no control over who had access to the chemotherapy stored in the ward refrigerators nor in the Pharmacy.

The ward refrigerators containing chemotherapy were not locked.

There were no separate areas for the storage of intrathecal and intravenous drugs in the ward refrigerators nor in the Pharmacy.

When Staff Nurse Vallance retrieved Mr Jowett’s chemotherapy from the Day Case Unit refrigerator she did not perform the checks as set out in the Ward E17 “Procedures for the Administration of Systemic Chemotherapy.”

Patients were not included in the intrathecal drug administration checking procedure.

The administration of the intrathecal injection to patients was undertaken before the intravenous injection.

The “QMC Drug Custody and Administration Code of Practice” document had not been effectively distributed so that not all the medical staff in QMC, in particular those who worked on Ward E17, were aware of its existence.

An authorised Registrar or Consultant was not formally scheduled for duty on that Thursday afternoon.

There was no easily recognisable cue to the nursing staff to indicate that Dr Mulhem and Dr Morton should not undertake the intrathecal administration of chemotherapy to patients.

Protocols

There was no explicit protocol;

- For the medical staff to follow to ensure that they had retrieved the correct chemotherapy for the patient whom they were about to treat.
- For including patients in the drug checking procedure for the intrathecal administration of chemotherapy.
- For the medical staff to follow when carrying out the administration of intrathecal chemotherapy.
- Stating who could collect, transfer and store in the ward's two refrigerators chemotherapy collected from 'B' Floor Pharmacy.
- Stating who had authority to retrieve chemotherapy from the two ward refrigerators and what responsibilities they had for checking it if they were retrieving it for someone else.
- Stating that intrathecal and intravenous drugs must not be released from the SPU on the same day for the same patient.
- Stating who had authority to dispense chemotherapy from the refrigerator in 'B' Floor Pharmacy.

Two versions of the "Haematology Guidelines and Protocols" were allowed to be on the ward at the same time. One of the versions did not possess the warning about not giving Vincristine on the same day as intrathecal drugs.

There was no warning in the "Haematology Guidelines and Protocols" stating that if Vincristine was inadvertently administered intrathecally it is almost always fatal.

Administration

The same "Chemotherapy Prescription Chart" is used for drugs with different routes of administration.

All the chemotherapy prescribed for a patient is recorded on the front of the chart, regardless of the routes of administration.

There was no space on the "Collection of Specials and Chemotherapy from the Dispensary by Ward Staff" sheet for the route of administration to be written in.

There was no space on the "Collection of Specials and Chemotherapy from the Dispensary by Ward Staff" sheet for the person dispensing chemotherapy to sign, thus creating a break in the audit trail.

There was no explicit record of SHOs and SpRs receiving Ward E17 guidelines and protocols.

Training

There was no formal Induction Course for SHOs or SpRs on Ward E17.

There was no formal evaluation to ensure that SHOs had read and correctly understood all Trust and Ward E17 protocols and guidelines that apply to her or him before being allowed to treat patients.

There was no formal training in procedures for SpRs on Ward E17.

There was no formal evaluation to ensure a new SpR had read and correctly understood all Trust and Ward E17 protocols and guidelines before being allowed to treat patients.

There was a failure to train SpRs to have some knowledge regarding the administration of intravenous chemotherapy.

Communications

Patients were not explicitly included in the drug checking procedure carried out by the medical staff prior to the administration of intrathecal chemotherapy.

Mr Jowett did not inform Ward E17 that he would not be keeping his morning appointment and that he would be arriving for his chemotherapy late on Thursday afternoon.

Dr Gould and Dr Grimley did not explicitly state and then check that Dr Mulhem had understood what they meant by the term “shadowing”.

Dr Mulhem made an informal verbal request for Staff Nurse Vallance to retrieve Mr Jowett’s chemotherapy from the ward refrigerator.

Dr Musuka did not write into Mr Jowett’s notes that he wanted to speak with him as soon as he arrived.

There was a failure to publicise the “QMC Drug Custody and Administration Code of Practice” document and as a result not all the medical staff in QMC were aware of its existence. In particular, it had not been drawn to the attention of the medical staff on Ward E17.

There was a failure to publicise to all staff on Ward E17 the danger posed to patients by the cytotoxic chemotherapy drug Vincristine.

Dr Morton did not bring to Dr Mulhem’s attention with sufficient urgency his unease regarding the intrathecal administration of Vincristine to Mr Jowett.

Technical

It would appear that the similarity of the labelling, packaging, size of syringe and volume of solution to be administered compounded the issues noted above.

The syringes used to administer intrathecal and intravenous chemotherapy can both be connected to the spinal needle used for the lumbar puncture.

National Issues

The UKALL Trial XII protocol explicitly instructs physicians to administer intrathecal and intravenous chemotherapy on the same day, in opposition to good practice.

The explicit formal training of physicians in the practical administration of chemotherapy appears to be variable, and consequently learning will on occasions only be from their local environment. This clearly leads to the possibility of different approaches and beliefs regarding the practical administration of chemotherapy. The death of Mr Jowett strongly suggests that these differences can sometimes conceal poor practice.

Recommendations for the administration of intrathecal chemotherapy

The list of recommendations that follows is intended to address the range of issues revealed by the evidence presented to this inquiry. The recommendations that have been made, however, should not be considered to be a definitive set of actions that will guarantee the safety of patients who have combined intrathecal and intravenous chemotherapy under all circumstances. Medicine, technology and clinical management practices change and, therefore, given that no one can prespecify their own ignorance, constant vigilance and a robust safety culture will always be required if such accidents are to be prevented in the future.

Although the recommendations made below are intended specifically to prevent a recurrence of the events that led to the death of Mr Jowett, a number of them do reflect the advice already published in JCCO (1994).

Operational practices

Pharmacy

Intrathecal and intravenous drugs must be stored in different areas.

Intrathecal drugs should always be dispensed at a different time to that of intravenous chemotherapy and only following written proof that any intravenous drugs for the named patient have been administered.

Intrathecal drugs must only be dispensed during normal working hours.

Only a pharmacist with training in oncology should be allowed to issue drugs for intrathecal administration.

Intrathecal chemotherapy should always only be issued by the pharmacist directly to the doctor who is going to administer it.

There should be a list in the Pharmacy of medical staff who have been authorised to administer intrathecal chemotherapy.

Intrathecal chemotherapy drugs should always be packed and transported as single items, never in a collective pack with treatments for administration by other routes.

All approved Trust protocols and procedures relating to chemotherapy should be lodged in the Pharmacy.

The “QMC Drug Custody and Administration Code of Practice” must be distributed to every department within QMC and a signature obtained from the physician acting as Clinical Lead to demonstrate that it has been brought to their attention.

Wards

A doctor receiving chemotherapy must check before signing the “Collection of Specials and Chemotherapy from the Dispensary by Ward Staff” sheet that intrathecal and intravenous drugs have not been dispensed together by mistake.

Intrathecal chemotherapy must always be transported as single items and never in a collective pack with drugs for administration by other routes.

Intrathecal drugs must always be stored separately from other drugs.

Only the doctor who is to administer intrathecal chemotherapy should retrieve drugs from the ward storage unit.

Ward refrigerators containing chemotherapy must be locked at all times unless an authorised member of staff is retrieving drugs.

Patients must be reviewed by a consultant or an appropriately trained and nominated deputy before intrathecal chemotherapy is administered. This is to ensure that the patient is fit for treatment, the correct chemotherapy has been prescribed, the correct tests have been completed and arrangements have been clearly made for the chemotherapy to be administered by the appropriate medical staff.

Intravenous drugs must always be administered before intrathecal chemotherapy.

Only a Consultant or authorised SpR must be allowed to administer intrathecal chemotherapy to patients.

An SHO must not be allowed to administer intrathecal chemotherapy.

After formal training into the dangers associated with the administration of intrathecal chemotherapy, an SHO may insert the lumbar puncture needle but must not play any further part in the procedure. It is only a consultant or authorised SpR who may actually administer the drug.

Intrathecal drugs should be administered in an area where no other cytotoxic drugs are given or stored.

Intrathecal drugs must only be administered during normal working hours.

Medical staff, when preparing to treat a patient with intrathecal chemotherapy, must use a formal checking procedure such as the one used by nurses for the administration of intravenous chemotherapy. This should also include a nurse, patient and, if appropriate, a relative or guardian in the checking procedure.

The Lead Clinician must ensure that SHOs and SpRs who are new to the department are provided with a formal period of induction. This should include the provision of QMC and ward guidelines and protocols, and the new member or members of staff should sign to acknowledge receipt of them.

Protocols

Wards

An explicit procedure for the administration of chemotherapy should be produced and given to all members of the medical staff who administer intrathecal chemotherapy. This should explicitly state that a nurse, patient and, where appropriate, a relative or guardian are always to be included in the checking procedure. It must also warn that Vincristine is almost always fatal when administered intrathecally.

A procedure should be produced stating the circumstances under which chemotherapy may be collected, transported and subsequently stored on the ward.

Separate procedures should be produced stating the circumstances under which intrathecal and intravenous chemotherapy is retrieved from ward storage.

All copies of the old version of the wards "Haematology Guidelines and Protocols" must be removed from the ward immediately and destroyed.

A document version control and recording system must be introduced to ensure that only the latest editions of guidelines and procedures are available to staff.

Copies of all departmental procedures relating to chemotherapy must be lodged in every location where they may be required for consultation.

Pharmacy

The Pharmacy should produce a procedure that states the criteria required for a pharmacist to dispense intrathecal drugs.

Administration

Intrathecal drugs should be prescribed on a separate prescription chart to drugs administered intravenously. The chart on which intrathecal drugs are prescribed should also be of a different and easily identifiable colour to that used to prescribe intravenous drugs.

The colour of an intrathecal prescription chart should match the colour of the label attached to a syringe containing the drug, as should the identifying mark on the packaging. Please see "Technical" section below.

Prescriptions charts should unambiguously specify the route as "intrathecal" and there should be sufficient space on the chart to write it in full.

A new form should be created so that there is space on "Collection of Specials and Chemotherapy from the Dispensary by Ward Staff" sheet so that the route of administration can be written in full and also the name of the person who dispenses the chemotherapy.

Training

A formal induction course should be created for both SHOs and SpRs appropriate to their needs with regard to the practical administration of chemotherapy. But, as a minimum it must cover all potential clinical hazards on the ward and the danger posed to patients if Vincristine is administered intrathecally.

There should be a formal oral or written assessment to ensure that SHOs and SpRs have read and understood all the Trust guidelines and protocols before being allowed to practice their respective roles in the administration of intrathecal chemotherapy.

New SpRs should receive formal training in the practical administration of intravenous and intrathecal chemotherapy on appointment. Consultants and staff grade doctors should have regular formal updates of training in the practical administration of chemotherapy.

A form should be created for SHOs and SpRs to sign to indicate that they have received their copies of QMC and ward guidelines and protocols.

Communications

A nurse, the patient and, where appropriate, a relative or guardian should always be included in the checking procedure carried out by medical staff prior to the administration of intrathecal chemotherapy.

If a patient should be late for their appointment but their arrival is still within normal working hours there should be sufficient flexibility in the ward's working arrangements to allow their treatment to proceed. However, if a patient arrives for their planned chemotherapy out of normal working hours, then a new appointment must be made.

During any period of supervised practice or "shadowing" it should be made explicit in writing what the responsibilities of practitioners are and what limits there are to their clinical activities. After which a verbal check should be made to ensure that they completely understand the position.

All verbal requests relating to patients or drugs should be clear as to what action is required and, if the request cannot be complied with immediately, it should be recorded in writing in the appropriate place, i.e. handover diary or a patient's notes and preferably both.

There should be a communications exercise to advertise the "QMC Drug Custody and Administration Code of Practice" throughout the Trust.

There should be a targeted communications campaign to ensure that all those who come into contact with chemotherapy are constantly aware of the danger posed by Vincristine.

There should be a communications promotion to encourage all the staff in the Trust to challenge anyone, no matter how senior their position, if they have reason to believe that something is amiss.

Technical

The labelling and packaging used for intrathecal drugs should be distinctive and be colour coded to match the prescription chart.

The labels should have the route of administration in the largest size Font used on the label and be in bold type. The remainder of the information should be in normal type.

The Pharmacy staff should dilute the volume of Vincristine from 2ml to at least 20mls for adult patients as this would help reduce any confusion there might be with syringes, as intrathecal drugs are rarely given in such large quantities.

National issues

A new spinal needle with a connection that cannot fit Luer mount intravenous syringes should be introduced, in conjunction with a new syringe which can only be fitted to that specific spinal needle. Or, incorporating within this concept, a pre-filled syringe and spinal needle system for all drugs that are administered intrathecally should be developed and implemented.

The UKALL Trial XII should be modified so that at least one day separates the administration of intravenous and intrathecal chemotherapy. Intravenous administration of chemotherapy should always take place first.

There should be a system introduced nationally that covers all elements of the activities required to supply and administer intrathecal drugs to patients.

Within the only specialties that are allowed to prescribe systemic cancer chemotherapy (medical oncology, clinical oncology, paediatric oncology and haematology), there should be a specific, compulsory and formally taught course on the practical administration of chemotherapy for all new specialist registrars on entry into the grade. In addition, the Royal Colleges should jointly advise on the time interval required between refresher training courses for consultants and staff grades.

The development of National Chemotherapy Drug Chart Design whose colour coding scheme would match the labelling and packaging system is recommended for use with intrathecal drugs.

A review of the need for 2mg/2ml formulations of Vincristine, in particular the manufactured pre-filled syringes, should be undertaken.

Medical schools must specifically train medical students in the formal checking and administration of drugs. This skill must be practised in clinical placements.

Finally, when evaluating the results of someone else's mistake perhaps it would be useful if society as a whole would reflect upon the observation made by Turner and Pidgeon (1997: 135) in that:

"...if we are looking back upon a decision which has been taken, as most decisions, in the absence of complete information, it is important that we should not assess the actions of decision-makers too harshly in the light of the knowledge which hindsight gives us."

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Appendix 1

List of Witnesses

External Inquiry Queen's Medical Centre Trust Nottingham 12th February 2001

Written and Verbal Evidence

Sister D Crouch	Ward Manager Ward E17	
Staff Nurse J Vallance	Staff Nurse Ward E17	
Dr J Gould	Consultant Haematologist	
Dr C Grimley	Specialist Registrar	Clinical Haematology
Dr D Morton	Senior House Officer	Clinical Haematology
Dr C Musuka	Consultant Haematologist	
Dr F Mulhem	Specialist Registrar	Clinical Haematology
Mr J Graham	Ward Pharmacist Ward E17	
Ms J Kendall	Assistant Chief Pharmacist Pharmacy Department	
Ms C Shanahan	Ward Co-ordinator Ward E17	
Mr G Wilson	Assistant Technical Officer Pharmacy Department	

Written Evidence

Dr G Dolan	Consultant Haematologist	
Dr G Sidra	Specialist Registrar	Clinical Haematology
Dr M Partridge	Chief pharmacist	

Appendix 2

Extract from UKALL XII Protocol¹

MAINTENANCE CHEMOTHERAPY FOR THOSE RANDOMISED TO CHEMOTHERAPY

Patients completing the four cycles of consolidation continue on maintenance chemotherapy. This consists of:

Mercaptopurine 75 mg/m² p.o. daily.

Oral Methotrexate 20 mg/m² p.o. once a week (e.g. Friday).

Vincristine 1.4 mg/m² (maximum 2 mg) i.v. every 3 months.

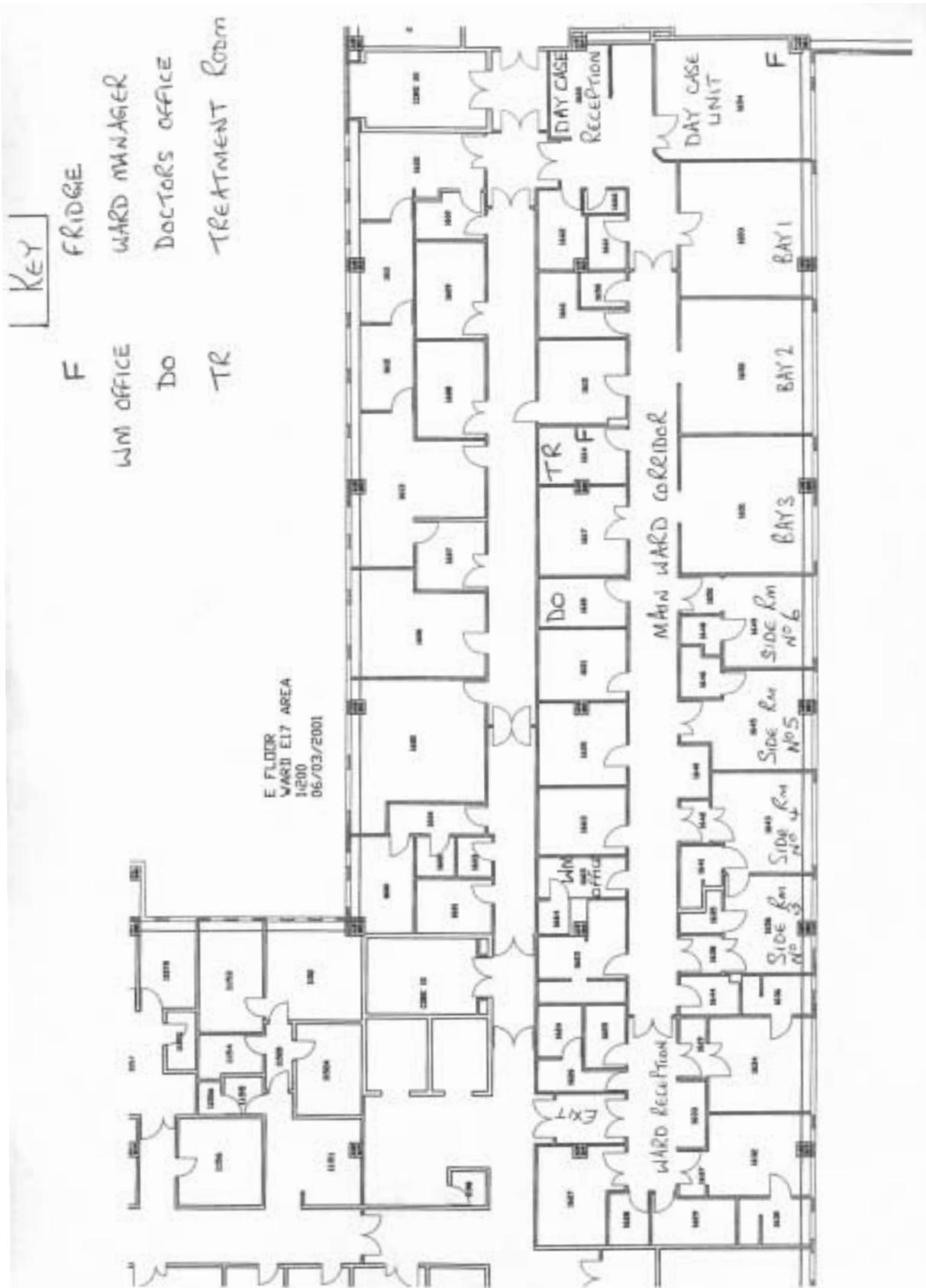
Cytosine arabinoside 50 mg i.t. every 3 months for 1 year (see CNS therapy).

Prednisolone (EC or not) 60 mg/m² for 5 days p.o. every 3 months at the same time as Vincristine.

Septtrin (co-trimoxazole) prophylaxis p.o. 2 tablets (960 mg) b.d. 3 days per week (Mon, Wed, Fri).

¹ Section 14. Acute Lymphoblastic Leukaemia Trial XII. Medical Research Council Working Party on Leukaemia in Adults. Revised May 1995.

Appendix 3



Appendix 4

Haematology Unit Ward E17

Procedure for the Administration of Systemic Chemotherapy¹

Definition:

Chemotherapy is the administration of Cytotoxic Medication either alone or in combination, in an attempt to reduce or eliminate malignant cells in the body.

- All systemic chemotherapy must be prescribed by the Registrar or Consultant responsible for the care of the patient.
- Details of the Chemotherapy Regimen should be recorded in the Medical Notes.
- Systemic Chemotherapy must only be given by Registered Nurses trained in the administration of Cytotoxic Therapy.
- Ensure patient has Full Blood Count on arrival on the ward, and notify the Registrar of results. Administration of the cytotoxic therapy will be authorised or delayed depending on these blood results.
- Check the prescribed Drug Chart for the specific Dose, Route and Mode of Administration.
- Obtain the cytotoxic therapy from the storage refrigerator and check the Bag and/or syringe for any sign of precipitation.
- Check the prescription chart against the chemotherapy bag or syringe ensuring the patient's NAME, DATE OF BIRTH and HOSPITAL NUMBER correlate.
- Check the DATE OF PRODUCTION and the EXPIRY DATE on the bag and/or syringe and the DATE OF ADMINISTRATION against the prescription chart.
- Place the prescribed bags and/or syringes in a prepared tray or on a treatment trolley.
- With a second qualified nurse check the bags and/or syringes containing the cytotoxic therapy against the written prescription prior to approaching the patient. This should involve checking the patient's NAME, DATE OF BIRTH and HOSPITAL NUMBER, the DATE OF PRODUCTION, the EXPIRY DATE and the DATE OF ADMINISTRATION.

¹ "Procedure for the Administration of Systematic Chemotherapy" issued on Ward E17 Queen's Medical Centre, Nottingham.

- If the prescription is in order take the prepared tray or trolley with the second qualified nurse to the patient's bedside.
Confirm that the patient is the patient for whom the prescription chart is made out for by asking the patient's NAME and DATE OF BIRTH and confirming their HOSPITAL NUMBER, checking this against the Prescription Chart and the Bags and/or Syringes. In addition check the INFUSION RATE, ROUTE and MODE OF ADMINISTRATION with another qualified nurse (ie; Bolus Medications will always be given through a fast flowing drip).
- If the Patient Identification, Written Prescription and Information on the Bags and/or Syringes containing the cytotoxic medications correlate then, WASH YOUR HANDS, select an appropriate cannulation site and cannulate the patient immediately prior to administering the cytotoxic drugs. (Cannulation will not be necessary if the patient has a Hickman Line).
- Prior to administration of the cytotoxic therapy explain to the patient the reason for its administration, what effect it will have, how it will be given and any side effects the patient may experience. Check INFORMED CONSENT has been given at this time.
Ask the patient to inform you immediately if they detect any sensations such as pain, itching or burning at the site of administration.
- Administer antiemetics as prescribed prior to administration of cytotoxic therapy.
- While infusing the cytotoxic medication at the appropriate rate and in the appropriate way monitor the patient constantly for any adverse effects eg; swelling at the cannula site, redness, pain or itching or any unusual sensations experienced by the patient who has a Hickman Line in situ.
- Check for the patency of the vein or Hickman Line periodically by attempting to draw blood back into the giving set, (if blood can be drawn back then the vein is considered patent).
- Should you detect any adverse problems or signs indicative of EXTRAVASATION having taken place then STOP THE ADMINISTRATION of the cytotoxic drug IMMEDIATELY and contact the Medical Staff, put the Extravasation Procedure into effect. (See Extravasation Procedure).

Appendix 5

Section on chemotherapy from “Haematology Guidelines and Protocols”¹

Chemotherapy

There is a more detailed protocol for administration of cytotoxics.

All systemic chemotherapy must be prescribed by Registrar or Consultant

Allopurinol and **IV fluids** are essential when dealing with bulky disease to prevent Tumour Lysis Syndrome

Details of chemotherapy with doses given should be duplicated within the medical notes

Ensure the prescription refers to the patient (check Name, DoB, Hospital No)

Always confirm chemotherapy bag or syringe corresponds with the prescription

Check infusion rate

Fast flowing drips are used to carry bolus IV cytotoxics

Stop infusion as soon as extravasation is suspected

Extravasation

Clinical indicators of extravasation are

Pain
Redness
Swelling

Immediately

Stop the infusion

Leave the Venflon **in situ**

Attempt to withdraw as much fluid as possible from the venflon – discard syringe into cytotoxic bin

Inform senior staff

Ice pack on most extravasation (except vincristine/vinblastine/vindesine use a warm compress)

Consider injecting hydrocortisone or dexamethasone into surrounding skin

Apply hydrocortisone 1% cream to area (and continue for several days)

Analgesia as appropriate

Document incident carefully in notes – consider photographing area affected

1 “Haematology Guidelines and Protocols” issued on Ward E17 Queen’s Medical Centre, Nottingham

Intrathecal Chemotherapy

NEVER mix intrathecal and intravenous chemotherapy on the same trolley or table

Should only be given under direct supervision by Registrar

Only Methotrexate, Cytosine (aka Cytarabine) and Hydrocortisone are given by this route

It should never be given on the same day as IV Vincristine.

4. **Delayed Vomiting** may occur more than 48 hrs post administration of chemotherapy. HT antagonists are not effective in this situation.

METOCLOPRAMIDE 20 mg po or iv qds

DOMPERIDONE 20mg po 6-8 hrly

If this fails add

DEXAMETHASONE 4mg po tds

5. **Anticipatory Vomiting** is a learnt response if previous chemotherapy has not been adequately covered. It is neurogenic in origin and does not respond to usual anti-emetics. It may be brought on by the thought of chemotherapy, or even associated stimuli eg the smell of rubber gloves, entering the ward etc

LORAZEPAM 0.5 mg po bd

Dexamethasone may be helpful in severe cases

Appendix 6

SHOs Ward E17¹

Ward E17 is an 18 Bedded Haematology Unit consisting of a ward area which includes 6 Side Rooms and 3 Bays of 4 beds each. The Unit also runs a Day Case Unit 5 days a week. Four of the beds on the ward are at the moment designated as Cardiac Medical Beds.

The Day Case Unit is run by Senior Nursing Staff (E, F, and G grades) who will;

Carry out Venepuncture

Take Blood Cultures

Cannulate

Administer Blood, Platelets, IV Medication etc

Administer Cytotoxic Chemotherapy

Venesect

Prescribe various Medications both Oral and IV

Carry out 12 Lead ECG's

Senior Staff rotate through the Day Case onto the Ward and so will also carry out these tasks on the main ward.

Most of the Junior Staff (D Grades) can also carry out most of the above procedures on the ward.

With regard to covering Day Case most of your time will be spent Reviewing Patients. The patients who require reviewing will be pointed out by the Nurse covering Day Case or by the Day Case Ward Receptionist.

Could we please ask you to not all go to lunch at the same time as in the past we have had problems with not being able to get medical staff to see patients in Day Case between 12.00am and 2.00pm as they have all gone to lunch at the same time.

This causes problems in that patients are having to wait around unnecessarily and they are also blocking chairs required for the afternoon patients.

Regarding Ward Rounds, Nursing Staff do not usually go around with the Medical Team except on Tuesday Afternoons and for the Grand Round on Friday Mornings. The Ward Sister usually attends these Ward Rounds, if she is not available the most senior nurses on that shift attends.

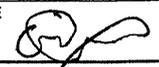
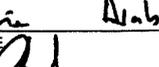
Following the normal ward rounds during the week the usual procedure is for one of the SHO's to "Handover" to the Senior Nurse on the ward for that shift as soon as the ward round is completed, this allows us to carry out required procedures and obtain TTO's and Discharge any patients more expediently.

1 "SHOs Ward E17" issued on Ward E17 Queen's Medical Centre, Nottingham.

Ward E17 has an Open House Policy in that patients can contact the ward directly or drop into the ward if they feel they have a problem. We find that it is easier for all concerned if they come straight to the ward rather than sit in GP admissions or A&E for a few hours. It also means that the SHO's are not being called to A&E all the time and you are able to see them in a better environment.

The Time Table and enclosed Haematology Guideline and Protocol Pack will answer most of your questions regarding ward requirements and the treatment and care of haematology patients, but if you have any questions about ward procedure or anything else feel free to ask any of the Nursing Staff or the Ward Sister.

Appendix 7

REGULAR PRESCRIPTIONS		CYCLE No.				CYCLE No.				CYCLE No.						
DRUG (Approved Name) VINCRISTINE		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY				
SIGNATURE A 		ROUTE i.v.	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE			
DRUG (Approved Name) CYTOSINE ARABINOSIDE		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY				
SIGNATURE B 		ROUTE I.T.	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE			
DRUG (Approved Name) Vincristine		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY				
SIGNATURE C 		ROUTE w	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE			
DRUG (Approved Name) Cytosine Arabinoside (IT)		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY				
SIGNATURE D 		ROUTE I.T.	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE			
DRUG (Approved Name)		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY				
SIGNATURE E		ROUTE	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE			
DRUG (Approved Name)		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY		DOSE	TIME	GIVEN BY				
SIGNATURE F		ROUTE	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE	PHARM.	SIG.	DATE			
DRUG (Approved Name)		Dose	Date	Time	Given by	P	Dose	Date	Time	Given by	P	Dose	Date	Time	Giv b	
SIGNATURE G		ROUTE	Sig.				Sig.					Sig.				
DRUG (Approved Name)		Dose	Date	Time	Given by	P	Dose	Date	Time	Given by	P	Dose	Date	Time	Giv b	
SIGNATURE H		ROUTE	Sig.				Sig.					Sig.				
SPECIAL INSTRUCTIONS (e.g. ECG, CXR, LFTs)		Hb					Hb					Hb				
		Wbc's					Wbc's					Wbc's				
		Platelets					Platelets					Platelets				
		OTHER INFORMATION					OTHER INFORMATION					OTHER INFORMATION				

Appendix 8

to start 6/6/2000

TREATMENT REGIMEN

ACRONYM: UKALL 12 - Maintenance

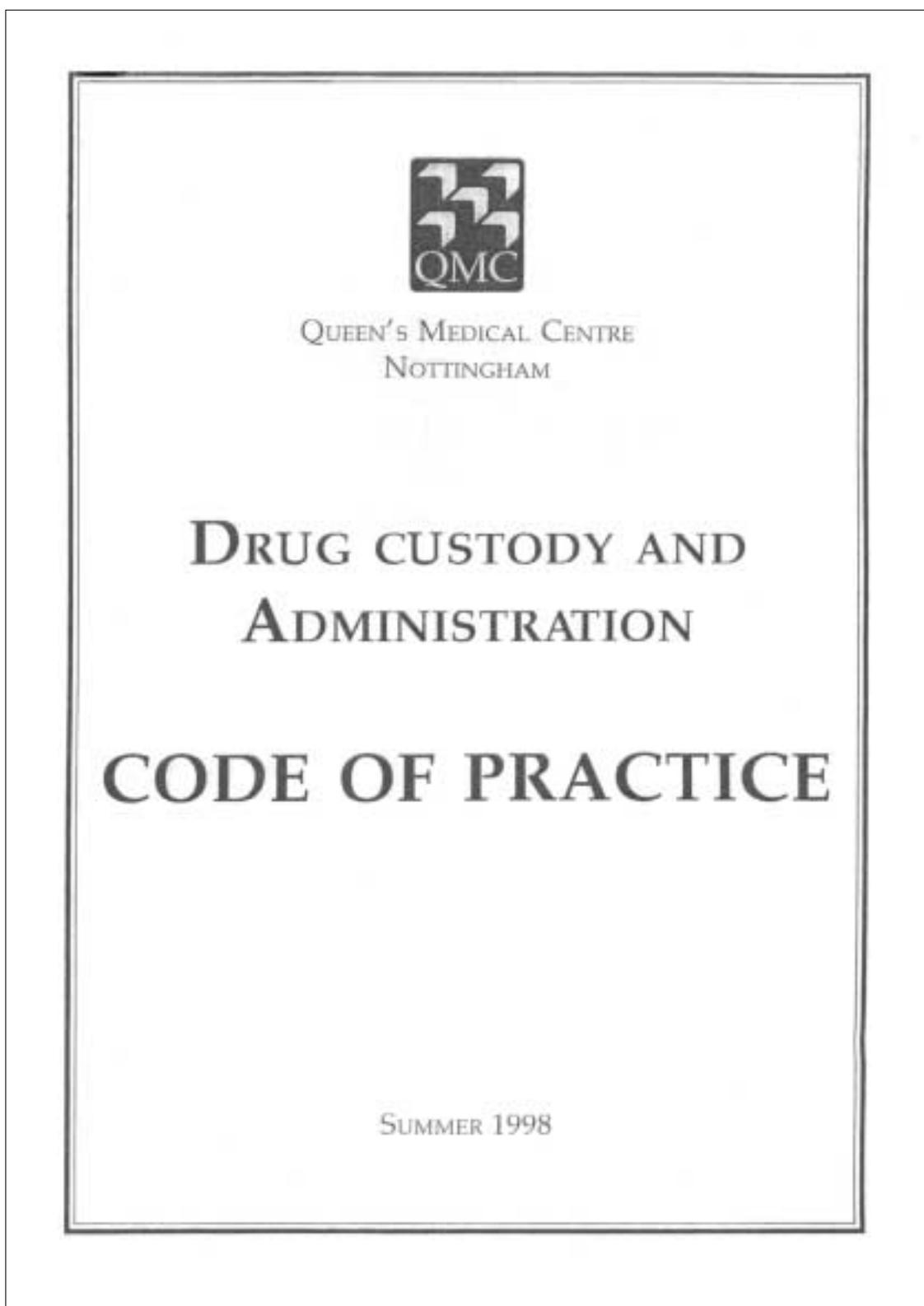
FREQUENCY OF CYCLE:

DATE	DRUG (Approved Name)	DOSE PER M ² or Kg	ACTUAL DOSE	DAY OF ADMINISTRATION	SIGNATURE
6/6/00	CYTOSINE ARABINOSIDE i.v.	50 mg	—	3 monthly	
	VINCRIStINE i.v.	1.4 mg/m ²	2 mg	3 monthly	
	PREDNISOLONE P.O. 5/7	60 mg/m ²	120 mg	3 monthly	
	GMP	75 mg/m ²	—	o.daily	
	METHOTREXATE P.O.	20 mg/m ²	40 mg	3 weekly	
	COTRIMOXAZOLE P.O.	960 mg	o.daily	—	

ONCE ONLY AND PRE MEDICATION DRUGS

DATE	TIME	DRUG (Approved Name)	ROUTE	DOSE	SIGNATURE	GIVEN BY	PHARM

Appendix 9



10. ADMINISTRATION OF MEDICINES BY NURSING STAFF

10.1 Responsibility

The nurse in charge is responsible for ensuring that standards for drug administration fall within the requirements of this Code. The registered nurse administering the medication will be accountable for his/her practice in accordance with UKCC Standards for the Administration of Medicines (1992) (refs).

The registered nurse carrying out the medicines administration or check should understand the prescription and should have knowledge of the common indications, side-effects and dosages of the medicine prescribed.

10.2 Authorisation

10.2.1 **A nurse must only administer a medicine against a practitioner's prescription or in accordance with a Group Protocol.**

10.2.2 Medicines must only be administered by:-

- medical or dental practitioners,
- **a registered nurse or midwife**, (as in section 1.1), including student midwives, already registered as in Section 1.1.
- **a pre-registration student nurse or pre-registration student midwife** as part of their training, but only under supervision of a registered nurse who must assume accountability for the correct administration and recording of the medicines prescribed.

On childrens wards parents will sometimes participate in medicine administration, (see Section 11 - Prescription and Administration of Drugs in Children).

Health care assistants and nursing auxiliaries have no role in medicines administration.

10.2.3 The Nottingham Guide to Intravenous Therapy (refs) gives detailed guidance for the administration of intravenous drugs.

The addition of drugs to intravenous fluids and the administration of intravenous drugs may be undertaken by registered nurses who can demonstrate relevant theoretical knowledge and who have been assessed as competent in accordance with current QMC "Scope of Professional Practice" policy (see refs.).

10.2.4 First doses of intravenous drugs

Following an assessment of the risks it has been agreed that **first doses** of intravenous drugs may be given by registered nurses assessed as competent as above, unless the drug is designated 'doctor only' in the Guide to Intravenous Therapy. (See refs.).

10.3 Checking

- 10.3.1 It is now the UKCC's view (refs) that registered nurses who have demonstrated the necessary knowledge and competence should be able to administer medicines without involving a second person as witness. Nonetheless individual nurses may consider that the preparation and administration of medicines in the presence of a second person (normally another nurse or in exceptional circumstances a doctor or a pharmacist) may be justifiable in improving patient safety. Medicines administered by a student nurse must be supervised by a registered nurse and experienced nurses may consider it necessary from time to time to supervise drug preparation and administration procedures by the less experienced in a training capacity and as an aid to service quality.
- 10.3.2 With children (whether on a children's or adult ward) two nurses are usually involved in the procedure (see section 11).
- 10.3.3 Except where non-administration would be prejudicial to patient care the following medicines must be checked by two persons one of whom must be a registered nurse. Except where the drug is administered by a doctor the administration must be by a registered nurse or by a student nurse under the direct supervision of a registered nurse. As in 10.3.1. the witness may be another health professional.

All intravenous injections, whether by bolus or infusion (see 10.2.3) Nurse administering intravenous drugs should be especially aware of the possibility of anaphylactic reactions. NB First doses of intravenous drugs may be given by registered nurses (as in 10.2.3). I.M. Adrenaline is available in cardiac arrest boxes and may be administered without the need for a prescription.

All Controlled Drugs.

All injections drawn from multi-dose vials.

Insulins.

Heparin.

Anticoagulants.

Cytotoxic preparations.

Cardiac glycosides (-Digoxin) etc given by injection.

Vaccines.

Where a calculation is necessary.

10.4 Procedures for Checking, Administration and Recording of Medicines

10.4.1 Before administration of a medicine, the nurse must :-

- check that the patient's name and hospital number as stated on the patient's identity bracelet is the same as that on the prescription chart, eg by asking the patients name and date of birth.
- read the prescription carefully. The medicine must not be given unless the prescription, dose and route of administration are clearly understood; 'As Required' medicines should only be administered for the stated indication. If the prescription is in any way unclear the prescriber must be consulted.

- **check** that the prescribed dose has not already been given. With 'as required' medicines, the size and timing of the previous dose should be checked before proceeding.
- **select** the medicine required, check the label with the prescription and that the expiry date, if stated, has not been passed.
- **confirm** with the prescription.
 - the name and form of the medicine
 - the route of administration
 - the calculation (if any)
 - the dose prescribed
 - the date and time of dosage
 - the time of last dose

10.4.2 When the dose has been given the registered nurse must **initial** in the appropriate column of the prescription chart at the time of administration. Where a **second person** is witnessing the administration they should also initial in this column.

10.4.3 If a **drug is refused**, a circled (R) should be entered on the prescription chart. If omitted for any other reason, eg nil by mouth, a record must be made on the administration section. In addition, it may be necessary to inform the prescriber of this non-administration and make a record in the nursing documentation.

10.4.4 Medicines dispensed for an individual patient must be administered only to that patient. Under exceptional circumstances medicines dispensed for one patient may be used for another but the ward pharmacist should be notified as soon as possible.

10.5 Oral Syringes

Oral syringes of a distinct design (not compatible with luer lock needles etc) are available to facilitate the measurement and administration of liquid doses in children and the elderly. Care must be taken to separate these from parenteral syringes during medicine rounds. **Parenteral syringes must not be used for the purpose of administering oral medicines.**

10.6 Disposal of Medicines prepared for Administration

The medicines should be disposed of in accordance with QMC waste disposal policy. (See refs). However the contents of open ampoules and other liquid medicines which are not required may be flushed away, with the exception of cytotoxic drugs and vaccines where the full procedure should be followed.

10.7 Controlled Drugs - administration, records and disposal

10.7.1 The administration of by any route of all Controlled Drugs for which records need to be kept **must be witnessed**, (see Section 10.3).

10.7.2 Every column in the Controlled Drug register must be completed without delay:-

- date and time of administration;
- name of patient;
- dose administered;
- signature of the registered nurse/doctor administering the dose and that of the witness;
- balance of stock remaining.
- where a part ampoule remains and is disposed of as in 10.6 a record of disposer and witness should be made.

10.7.3 Disposal of Controlled Drugs prepared for administration

The contents of partly used ampoules, unused tablets or liquid medicines must be disposed of by flushing away with minimum delay in the presence of a witness. (See 6.2.3 and appendix I).

In addition:-

- Controlled Drugs in liquid form once measured must not be returned to the original container.
- any tablets refused must not be returned to their original container.
- unbroken ampoules must be returned to their original container and the return witnessed carefully ensuring that the ampoule is being returned to the correct box and that the batch numbers on the ampoules correspond with those on the container.

10.8 Preparation of Drugs for Administration by Medical Staff

Where a drug is prepared by a registered nurse/operating department assistant/Practitioner and administered by a doctor, the following must be undertaken:

- the drug must be prepared in the presence of the doctor, unless already prepared in the Pharmacy.
- if for any reason this is not possible, e.g. cardiac-arrest, the vial/container from which the drug was taken must be retained and shown to the doctor before administration.
- the doctor and registered nurse or operating department assistant/practitioner must follow the procedure for checking and administering drugs as described in Section 10.4.

10.9 Administration of Drugs by Medical Staff

10.9.1 The responsibility for safe preparation and administration lies with the doctor administering the drug. Medical staff must adhere to all the safety guidelines in the Code when administering drugs.

10.9.2 Solutions etc for topical use will often be prepared by a nurse on the doctor's behalf. Although nurses have responsibility for the safe and accurate preparation of such solutions, the ultimate responsibility rests with the doctor who applies the solution. He must satisfy himself regarding the identity and strength of the preparation.

Appendix 10



QUEEN'S MEDICAL CENTRE
NOTTINGHAM

**DRUG CUSTODY AND
ADMINISTRATION
CODE OF PRACTICE**

SUMMER 1998

15. **PRESCRIBING, DISPENSING AND ADMINISTRATION OF CYTOTOXIC CHEMOTHERAPY**

15.1 Particular care is needed when a patient is treated with cytotoxic chemotherapy. Separate booklets, for children and adults, giving detailed advice are available on the relevant unit.

15.2 Records of the prescription and administration of chemotherapy should be organised so that the overall plan of treatment given and intended is clear. A blue chemotherapy chart suitable for many cases, is available.

15.3 **Prescribing.** Prescribers should be as senior and experienced as possible. Chemotherapy should be initiated by the consultant in charge, or by his designated senior registrar, and should be from standard protocols whenever possible. The consultant in charge must also ensure that any doctor who prescribes chemotherapy has adequate experience or specific instructions concerning dosage, route of administration and toxicity of all medicines he/she will prescribe. Senior House Officers (including those covering out of hours) must be given appropriate training at the beginning of their rotation.

The acronym of the regimen, if appropriate, and the current weight, height and surface area of the patient should be recorded on the treatment chart each time chemotherapy is prescribed.

The route of administration must always be stated on the prescription.

In the case of children, each prescription should specify which week of treatment is being prescribed.

15.4 **Dispensing.** When a new regimen is instituted, a copy of the full protocol must be supplied to pharmacy, and to the relevant wards. To enable the most economical use of expensive medicines, Pharmacy should receive adequate advance warning of intended chemotherapy, even where this is provisional and the final decision to prepare and administer the medicines depends, for example, on the patient's blood count.

The required medicines can then be prepared by Pharmacy to be ready for use at the time indicated.

Some cytotoxics deteriorate rapidly after reconstitution, and these should be used as soon as possible after receipt on the ward/clinic.

15.5 **Storage on the ward.** Some cytotoxics may be stored on the ward if the expiry allows. All preparations will have storage instructions on the pharmacy label. Cytotoxics for storage at room temperature should be locked in a designated cupboard. Those to be refrigerated should be locked in a designated drugs refrigerator, where the temperature is monitored daily to ensure it is in the range of 2.C - 8.C. Refrigerated products must be warmed to room temperature before they are administered to the patient.

- 15.6 Administration and Advice on Handling.** Parenteral cytotoxics should only be administered by appropriately trained medical staff or registered nurses who can demonstrate the relevant theoretical knowledge and have been assessed as competent in accordance with the QMC "Scope of Professional Practice" Policy (QMC 1997)(refs).

Any members of the medical or nursing staff who is unsure about any detail of the administration should not proceed, but should seek help and advice from a more senior and/or experienced colleague. Any ambiguity in the prescription must be discussed with the prescriber before administration takes place.

Administration must be organised and methodical. Always check the drug, dose, route, and patients name and hospital number before proceeding.

The appropriate healthcare professional (doctor, nurse, pharmacist) must take great care in advising and educating the patient/parent in all aspects of their chemotherapy including the usage and side effects of the treatment. Information leaflets should be available wherever possible.

- 15.7 Chemotherapy Card.** All patients undergoing chemotherapy treatment carry a card to alert doctors unfamiliar with them to the possibility of immunosuppression, agranulocytosis, or septicæmia.



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