

The Chief Executive of the Hospital Authority has received the attached Report on a Medication Incident of Intrathecal Administration of Vincristine in Prince of Wales Hospital ('Report') from the Special Investigation Panel on 24 August 2007. The Hospital Authority now publishes this Report in its entirety, except that the personal identifiers of the involved persons have been removed.

Report on
a Medication Incident of
Intrathecal Administration of Vincristine
in Prince of Wales Hospital

Special Investigation Panel

August 2007

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1. Executive summary

Overview

A medication incident of inadvertent intrathecal administration of vincristine, which was intended for intravenous administration, occurred in an ambulatory care unit in a public hospital on 15 June 2007. A special investigation panel was commissioned by the Chief Executive of the Hospital Authority to review the incident and to make recommendations to prevent similar incidents and this document is the report of that panel.

The panel recognizes that there were guidelines in place to support the safe administration of intravenous and intrathecal chemotherapy in the hospital and that no similar cases had been reported in the hospital and the Hospital Authority.

The panel has generated the present report based on information supplied to it, but recognizes that it could not be exhaustive within the limited time frame of the investigation. The panel does not have the ability to verify the accuracy of the information provided to it, although there was consistency in the statements of the various parties involved. The panel recognizes that the Hospital Authority will wish to review the findings of the panel and its recommendations along with submissions from others involved in the incident, which may provide additional relevant information, and welcomes such submissions.

The causes of this unfortunate incident are multiple, but can be broadly separated into 3 components:

1. "System factors" including the delivery to the ambulatory care unit of intravenous vincristine and intrathecal cytarabine together, to be administered at the same time and in the same location, and with imperfect labelling; also inadequate checking of the medication and route of administration.
2. "Education factors" leading to insufficient awareness that intrathecal administration of vincristine is likely to be fatal, that similar incidents have occurred elsewhere and that there are international guidelines to prevent them.
3. "Human error" that was related to the above factors, and such that failure to follow existing guidelines led to a fatal incident.

Summary of recommendations

The following recommendations are made to enhance the systems in place in the hospital and the Hospital Authority to minimize the further possibility of human error.

A To improve the System

Establish standard operating procedures in all public hospitals which administer intrathecal chemotherapy that are based on international guidelines. These should include:

- 1 Only specially trained and designated oncology staff should prescribe, prepare, dispense and administer cytotoxic medication.
- 2 Medical staff should use separate prescription sheets for prescribing intravenous vincristine and intrathecal chemotherapy.
- 3 The clinician administering intrathecal chemotherapy must be familiar with the patient and with the chemotherapy protocol.

- 4 Medical staff must use a formal checking procedure, involving a nurse who has received training about cancer chemotherapy (or another doctor), to ensure that the right drug is given at the right dose, by the right route, at the right time and to the right patient.
- 5 Specifically designated containers must be used both for transportation of intrathecal drugs from the pharmacy and for storage on the ward or ambulatory care unit.
- 6 All intrathecal drugs must be packaged separately and clearly labelled on the container(s) "For Intrathecal Use".
- 7 Intrathecal chemotherapy must only be administered in an area where no other cytotoxic drugs are available.
- 8 Intrathecal drugs must be administered at a different time from other systemically administered drugs.
- 9 Vincristine should be prepared in a small-volume intravenous bag when administered to adults and older children. For small children, dilution in a 10 to 20ml syringe is appropriate.
- 10 Vincristine should be clearly labelled on the bag and on the outer container "For Intravenous Use Only – Fatal If Given by Other Routes". Negative labels, such as 'Not for Intrathecal Use' must not be used.

The following is optional:

- 11 Patients or their families may be involved in the checking process.

B To improve Education

The medical oncology training program at the hospital follows the guidelines of the Hong Kong College of Physicians. It provides excellent bedside teaching but most learning is a by-product of clinical service. Discussion of inappropriate treatments (e.g. intrathecal administration of vincristine) may not take place during patient-centred teaching. Internationally, medical oncology training programs have evolved to allow a balance between education and service, and to include a syllabus to ensure coverage of all important information that should be known by medical oncologists. We suggest that the medical oncology training program at public hospitals be modified in line with international trends. Important modifications will be:

1. Protected time when trainees have no clinical responsibilities (e.g. one morning per week) to allow formal teaching that should include, amongst others, courses covering -
 - i. natural history and management of all common malignancies;
 - ii. properties of anti-cancer drugs including their modes of action, toxicities, mechanisms of resistance, etc.
2. Rotations when trainees can concentrate on particular types of malignancies such as haematological versus solid tumours. This will allow trainees to undertake procedures (including systemic treatment of leukaemia) during a period when they can become familiar with the relevant patients and protocols.

For efficiency, we suggest that the hospital explores the possibility of common formal teaching of medical oncologists with the other Hong Kong programs, and where appropriate, with programs in clinical oncology.

Medication incidents such as this one are less likely to occur if all members of the clinical team are educated to recognize potential hazards of the use of anti-cancer therapy. We therefore recommend regular in-service education (e.g. monthly formal presentations within protected time) for pharmacists and nurses working in the field of oncology. Such in-service education should emphasize knowledge about systemic treatment of cancer and should highlight international guidelines that are designed to prevent potential causes of medication error. We also encourage nurses and pharmacists to continue their education through relevant courses and other means.

2. Introduction

Salient points:

- A medication incident occurred involving intrathecal (IT) administration of vincristine
- A special investigation panel was set up by the Chief Executive (CE) of the Hospital Authority (HA)

A 21-year-old female, who had acute lymphoblastic leukaemia (ALL), was injected with a dose of vincristine via the IT route on 15 June 2007 during the maintenance phase of treatment in the Ambulatory Cancer Care Center (ACCC) of the Department of Clinical Oncology (DOC) of the Prince of Wales Hospital (PWH). The patient attended the Department of Accident and Emergency of PWH on 16 June 2007 and was admitted to DOC for in-patient care. The error was suspected on 18 June 2007. DOC confirmed the error and informed the patient's family on 20 June 2007. Burr hole and external lumbar drainage of cerebrospinal fluid were performed on 21 June 2007. The patient died on 7 July 2007.

A special investigation panel was set up by CE of HA, which manages all public hospitals in Hong Kong, to investigate circumstances surrounding the medication incident and to make recommendations to prevent similar incidents across HA.

The Panel was chaired by Professor Ian Tannock, Professor of Medical Oncology at the Princess Margaret Hospital and the University of Toronto in Canada. Other members were Professor Grace Tang, President of Hong Kong Academy of Medicine and Dr P Y Leung, Director (Quality & Safety) of HA (Appendix 1).

The Panel obtained written information from 21 people, visited ACCC, and interviewed 12 people to obtain an in-depth understanding of the systems in place in HA and issues pertaining to the medication incident (Appendix 2). The Panel also met with relatives of the deceased patient.

3. Background

Salient points:

- Vincristine is neurotoxic and must only be given via the intravenous (IV) route
- IT administration of vincristine is nearly always fatal
- Multiple medication incidents involving inadvertent IT administration of vincristine have been reported from overseas countries and have led to recommendations to prevent this from occurring in the future
- There have been no previous incidents of this type in Hong Kong
- Procedures followed in PWH to support safe administration of IV vincristine and IT chemotherapy were based on the '3 Checks and 5 Rights' procedure to be followed for all drug administration (Appendix 3)

However, the procedures followed in PWH did not require:

- Separate prescription, dispensing, delivery, storage, checking and administering of IV vincristine for patients who also need IT chemotherapy
- Medical staff to use separate prescription sheets for prescription of IV vincristine and IT chemotherapy
- The Pharmacy to deliver IV vincristine and IT chemotherapy separately and to highlight the warning messages on their labels
- IT chemotherapy to be given in an area with no other chemotherapy to be administered via other routes, and IV vincristine and IT chemotherapy to be administered at different times
- Medical staff to be assisted by specifically trained nursing staff and double checking to occur prior to administration of IT chemotherapy

3.1 Patient

The patient was first diagnosed with ALL in November 2005. She was treated by DOC of PWH with induction chemotherapy using the UK ALL XII protocol and achieved complete remission. She continued treatment according to the protocol, including central nervous system prophylaxis, consolidation treatment and most recently, maintenance chemotherapy. Parenteral drugs were given in ACCC.

According to the protocol, the medications to be used as maintenance chemotherapy (given orally unless otherwise indicated) are:

- 6-mercaptopurine 75 mg/m² daily
- methotrexate 20 mg/m² once per week
- vincristine 1.4 mg/m² IV push, every 3 months for 4 doses
- cytarabine 50 mg IT, every 3 months for 4 doses
- prednisone 60 mg/m² daily, days 1-5 every 3 months
- septrin 480 mg daily, for 3 days per week (Mon, Wed, Fri)

It was usual to administer IV vincristine and IT cytarabine on the same day in ACCC.

3.2 Vincristine

Vincristine sulphate (vincristine), a white to off-white powder, is administered intravenously, as a component of combination chemotherapy regimens for ALL, lymphomas and other tumours.

Vincristine was approved by the United States Food and Drug Administration (FDA) in July 1963.¹ It is very neurotoxic and must only be administered via the IV route. Inadvertent injection of vincristine into the spinal canal, i.e. IT administration, is nearly always fatal. The few patients who have survived have had severe and permanent neurological damage.

The characteristic clinical course following IT administration of vincristine is slow paralysis reflective of progressive, ascending myelo-encephalopathy. First signs are often stiff neck with lower limb or back pain followed by lower limb weakness, urinary retention (or frequency), absent reflexes and gradual loss of nerve and muscle function, culminating in respiratory failure and brain stem death.²

Despite promulgation of risk-reduction strategies worldwide, medication incidents involving inadvertent IT administration of vincristine have been reported repeatedly from overseas countries.

Up to July 2007, 55 overseas cases of inadvertent IT administration of vincristine have been identified since the first reported case in 1968.^{2,3,4}

¹ Center for Drug Evaluation, U.S. Food and Drug Administration. FDA oncology tools approval summary for vincristine. Rockville, MD: U.S. Department of Health and Human Services. Available from:

<http://www.accessdata.fda.gov/scripts/cder/onctools/summary.cfm?ID=35>

² Burgess, N. High-risk medication alert for vincristine injection: literature review. The Society of Hospital Pharmacists of Australia, December 2005. Available from:

[http://www.safetyandquality.org/internet/safety/publishing.nsf/Content/8C5C22A2427D2FC0CA257149001FBF31/\\$File/vlitera2.pdf](http://www.safetyandquality.org/internet/safety/publishing.nsf/Content/8C5C22A2427D2FC0CA257149001FBF31/$File/vlitera2.pdf)

³ Lagman, J. L. L. ; Tigue, C. C.; Trifilio, S. M.; Belknap, S. Buffie, C.; Bennett, C. L. Inadvertent intrathecal administration of vincristine. Community Oncology. January 2007, 4: 45-6. Available from:

<http://www.communityoncology.net/journal/articles/0401045.pdf>

The incident rate of inadvertent IT administration of vincristine is not known. The estimated rate of maladministration of vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) is 3 per 100,000 IT chemotherapy treatments.⁵

Recommendations have been made by various national and international organizations (e.g. the Australian Commission on Safety and Quality in Health Care⁶, the Institute for Safe Medication⁷, the Department of Health of UK⁸, the Joint Commission⁹, the World Health Organization⁴, etc) to prevent the inadvertent IT administration of vincristine, and these are posted on various web-sites. Although there are some variations in these recommendations, essential features are:

- Only specifically trained and designated oncology staff should prescribe, prepare, dispense and administer cytotoxic medication.
- All IT drugs must be packaged separately and clearly labelled both on the syringe and on the outer container 'For Intrathecal Use'
- IT doses must be delivered separately and preferably administered after drugs to be given by other routes are supplied and administered. IT chemotherapy should only be administered in an area where no other cytotoxic drugs are available.
- Specifically designated containers should be used both for transportation of IT drugs from the pharmacy and for storage on the ward or ambulatory care unit.
- Consideration should be given to developing novel methods for spinal drug delivery. Standard IV syringes should not be used for spinal administration.
- Vincristine should be clearly labelled both on the syringe and on the outer container "For Intravenous Use Only – Fatal if Given by Other Routes'. Negative labels, such as 'Not for Intrathecal Use' must never be used.
- Vincristine should be prepared in a small volume IV bag (minibag) rather than a syringe.
- Medical staff must use a formal checking procedure, involving an oncology trained nurse or other trained health professional, to ensure that the right drug is given at the right dose, by the right route, by the right method, to the right patient.
- Patients or their families may be involved in the checking process.

3.3 ACCC

ACCC at PWH was established in 2006 for provision of outpatient cancer care, including IV and IT chemotherapy. It is managed and staffed by DOC which has been responsible for the delivery of systemic cancer treatment since 1984.

ACCC has the following facilities: 2 waiting halls, 12 consultation rooms, 5 chemotherapy bed rooms (16 beds in total), 2 chemotherapy chair rooms (28 comfort chairs in total), 1 nurse station and 1 service station, 2 special treatment rooms and 1 oncology/haematology laboratory.

The cancer care services at ACCC are provided by a health care team which also supports other

⁴ Alert No. 115. World Health Organization. 18 July 2007. Available from:

http://www.who.int/medicines/publications/drugalerts/Alert_115_vincristine.pdf

⁵ An organization with a memory. Report of an expert group on learning from adverse events in NHS. 2000. Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4065083

⁶ Medication alert: vincristine can be fatal if administered by the intrathecal route. Australian Council for Safety and Quality in Health Care. Alert 2. December 2005. Available from: [http://www.safetyandquality.org/internet/safety/publishing.nsf/Content/8C5C22A2427D2FC0CA257149001FBF31/\\$File/v_alert.pdf](http://www.safetyandquality.org/internet/safety/publishing.nsf/Content/8C5C22A2427D2FC0CA257149001FBF31/$File/v_alert.pdf)

⁷ Medication safety alert: fatal misadministration if IV vincristine. Institute for Safe Medication Practice. December 2005. Available from: <http://www.ismp.org/Newsletters/acutecare/articles/20051201.asp>

⁸ Updated national guidance on the safe administration of intrathecal chemotherapy. Department of Health of UK. October 2003. Available from:

http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4064931

⁹ Sentinel event alert: preventing vincristine administration errors. The Joint Commission. July 14, 2005. Available from: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_34.htm

services of DOC (Table 1). All nursing staff have received basic training in safe handling of cytotoxic drugs. Two Nurse Specialists and three of the Registered Nurses have received formal advanced training, including a “Specialist Course in Cancer Nursing Care” and have received the “Certificate of Achievement in Chemotherapy Administration”. The average working experience of nursing staff in ACCC is 10 (range: 5-23) years.

Table 1 - Composition of the health care team in ACCC

	No. of medical staff	No. of nursing staff (actual work force in ACCC)	No. of support staff
Staff mix & no.	<ul style="list-style-type: none"> ■ Professor: 3 ■ Associate Professor: 1 ■ Senior Medical Officer: 1 ■ Associate Consultant: 1 ■ Specialist: 5 ■ Higher physician trainee: 4 ■ Basic physician trainee: 1 	<ul style="list-style-type: none"> ■ Nurse Specialist: 2 (1) ■ Registered Nurse: 13 (6) ■ Enrolled Nurse: 5 (2) 	<ul style="list-style-type: none"> ■ Clerk: 3 ■ General service assistant (GSA) (for patient care): 2 ■ GSA: 2 ■ Workman II: 4 ■ Medical laboratory technician I: 1 ■ Medical laboratory technician II: 1
Total	16	20(9)	13

Members of the health care team have defined responsibilities regarding administration of chemotherapy in ACCC (Table 2). When administering chemotherapy, medical staff are required to verify essential information such as the drug labels (intended recipient, correct drug name, correct dose, correct frequency, and correct route of administration). Nurses are required to double check with a second person to ensure that the right drug is given at the right dose, at the right frequency/time, and by the right route of administration for the right patient based on the principles of “3 Checks and 5 Rights” (Appendix 3).

DOC prepared a document titled “Haematology Oncology Service: Protocols and Treatment Guidelines” in May 2000. It is stated in the document that “(p.5) Vesicants e.g. vincristine ... should be administered as a slow IV push ... through the side access port of a freely flowing infusion of 0.9% saline or dextrose ... The ONLY cytotoxic drugs used intrathecally are: Methotrexate, Cytosine arabinoside (cytarabine), Hydrocortisone ... ***Never use any other cytotoxic drugs for intrathecal injection – fatal consequences may ensue.***”

There was no policy requiring separate prescription, storage, checking and administering of IV vincristine for patients who also need IT chemotherapy, and no regular/structured in-service education for nursing staff on oncology/chemotherapy. PWH had actively made effort to ensure safe medication administration, including promulgation of the drug administration procedure of 3 Checks and 5 Rights (Appendix 3).

Table 2 - Responsibilities of medical staff and nursing staff in ACCC

Responsibility	Medical staff	Nursing staff		
		NS	RN	EN
<u>Protocol & treatment plan</u> <ul style="list-style-type: none"> ■ Review chemotherapy treatment protocols before implementation for service ■ Draft Chemotherapy Administration Sheet for individual chemotherapy regimens for daily operation ■ Decide chemotherapy treatment for individual patients 	✓ Senior staff ✓ Senior staff & specialists	 ✓		
<u>Prescription</u> <ul style="list-style-type: none"> ■ Prescribe chemotherapy ■ Check prescription against treatment protocol before sending to pharmacy 	✓ Specialists & trainees		✓	✓
<u>Preparation & set up</u> <ul style="list-style-type: none"> ■ Prepare patients & equipment, including lumbar puncture (LP), & handling of drugs for both IV & IT chemotherapy 			✓	✓
<u>Administration</u> <ul style="list-style-type: none"> ■ Administer IT chemotherapy ■ Assist doctor to perform LP & IT chemotherapy ■ Administer IV chemotherapy bolus injection 	✓ Specialists & trainees in oncology (not for house officers) ✓ Specialists & trainees in oncology (not for house officers) (including vincristine)	 ✓ (excluding vesicant ones)	 ✓ ✓ 3 RNs with advanced training (excluding vesicant ones)	 ✓

3.4 Pharmacy

The Cytotoxic Drug Admixing Section of the Pharmacy of PWH provides service to DOC and ACCC. Preparation of all cytotoxic drugs is performed inside a negative pressure isolator, which is inside a clean room. The pharmacist in-charge, together with 3 resident pharmacists trained to perform cytotoxic drug admixing, participate in the preparation of cytotoxic drugs in rotation. Labels for chemotherapy orders are printed and checked by 3 staff (two dispensers and one pharmacist) upon receipt. A workman is responsible for the final packaging of the products and delivery to ACCC.

IT chemotherapy drugs are supplied in their original forms (powder or liquid vials). The drugs are prepared and administered at the bedside using aseptic technique by trained doctors who perform the lumbar puncture and administer IT chemotherapy. For IV chemotherapy drugs, the Cytotoxic Drug Admixing Section is responsible for the preparation of pre-filled syringes or infusion bags.

All chemotherapy drugs were supplied with a drug label affixed to the outside packing showing the patient's particulars, drug name, dose and route of administration. For vincristine, there was a warning on the label "For IV ONLY". For cytarabine, the warning on the label was "Use

IMMEDIATELY after being prepared". These warnings were printed in the same font style, size and colour as other information on the label. The messages "KEEP OUT OF REACH OF CHILDREN" and "HOSPITAL AUTHORITY" on the drug label were printed in red, which is a standard format for HA drug labels.

The Pharmacy did not deliver IT chemotherapy drugs and IV chemotherapy drugs separately.

In-service education of Pharmacy staff has been minimal. There were ad hoc emails and notices about drug safety and monthly newsletters on drug information but there was no formal educational or journal club.

4. Chronology of events

Salient points:

- IV vincristine and IT cytarabine were prescribed together on a prescription sheet, and dispensed together to ACCC following the standard operating procedures (IV vincristine in a prefilled syringe ready to be administered by trained doctors and IT cytarabine in its original form in a box, requiring specific preparation at the bedside using aseptic technique) and were put together on a trolley prepared for LP and IT chemotherapy administration
- The doctor performing the chemotherapy administration has more than 4 years of specialized training in Medical Oncology and has administered numerous IV chemotherapy drugs including vincristine, and has performed about 20 IT chemotherapy procedures
- The doctor and the nurse did not check the route prescribed for vincristine and were not aware of the warning on the drug label
- The doctor and the nurse were not aware that the vincristine dispensed in a pre-filled syringe was intended for IV injection
- The doctor aspirated the vincristine from the pre-filled syringe into a sterile syringe and vincristine was administered via the IT route
- The patient became ill, and was admitted to hospital
- The error was suspected three days after drug administration and subsequently confirmed
- The patient died
- Additional procedures relating to IT chemotherapy were implemented subsequently in PWH and in HA

4.1 Prescription of chemotherapy

On 15 June 2007, the patient attended ACCC for follow-up and maintenance therapy to prevent recurrence of her leukaemia. She was assessed in the morning by the Director of ACCC who is a specialist in Medical Oncology. *[The Director of ACCC is also accredited in Haematology / Haematological Oncology. He is a certified trainer for these two subspecialties in the Hong Kong College of Physicians.]*

At around 1pm, he prescribed electronically via the Medication Order Entry System the following:

1. VINCRISTINE SULPHATE injection
parenteral: 2mg daily for 1 days **fix period**
slow iv push, every 3 month x 4 doses
2. CYTARABINE injection 100mg/ml 10ml
parenteral: 50mg daily [Intrathecally] for 1 days **fixed period**
IT chemo, to be prepared and given by MO, every 3 month x 4 doses

The plan was to give the two chemotherapy drugs in ACCC in the afternoon. A copy of the prescription sheet was printed and attached with the clinical folder.

4.2 Preparation of drugs

A pharmacist assisted by dispensers, processed the prescription order in the Pharmacy. *[The pharmacist was trained for cytotoxic reconstitution service in June 2004 and delivered cytotoxic reconstitution service in rotation with other pharmacists since completion of training.]*

The pharmacist prepared the two chemotherapy drugs as follows:

- A pre-filled syringe of vincristine (2mg in 2ml in a syringe affixed with a dispensing label containing the patient's details, drug name, dose and the warning "For IV ONLY" enclosed within an overwrap (a black plastic bag) with a similar label) (Plate 1)
- A bottle of Cytarabine (100mg powder in original packing but with the diluent removed) affixed with a dispensing label with the patient's details, drug name, dose and the route "I.T." (Plate 2)

The two chemotherapy drugs were put together in a transparent plastic bag and delivered to ACCC (Plate 3).

4.3 Administration of chemotherapy

An Enrolled Nurse was assigned to prepare a trolley for LP and IT chemotherapy. *[The Enrolled Nurse has not received formal specialized training in oncology nursing or chemotherapy. She has 11 years of working experience in oncology. She has received training to assist medical staff to perform LP and administration of IV chemotherapy. She has not received any specialized training for administration of vincristine and IT chemotherapy.]*

A supporting staff, under the supervision of a Registered Nurse, put the two chemotherapy drugs on the top shelf of the trolley (Plate 4). The Registered Nurse was not aware of the two different routes of administration prescribed for vincristine and cytarabine, i.e. IV for the former and IT for the latter. *[The Registered Nurse has received formal specialized training in oncology nursing. She has 10 years of working experience in oncology.]*

A Resident Doctor was on duty in ACCC that afternoon. *[The Resident Doctor was qualified as a medical practitioner in UK in 2000. She underwent internal medicine training in UK as a Senior House Officer and obtained the membership of the UK Royal College of Physicians (MRCP) qualification in 2003. She was a Senior House Officer in a major cancer hospital (The Royal Marsden Hospital, London, UK) in 2003-2004 specializing in Medical Oncology. She joined DOC of PWH as a locum medical officer in April 2004 and as a Resident in 2005. She became a member of the HK College of Physicians in 2004. She passed two annual assessments of Higher Physician Training in Medical Oncology in 2005 and 2006 and is due for Exit Examination in 2007 to become a Fellow of the HK College of Physicians under the speciality of Medical Oncology. She has performed about 20 IT chemotherapy procedures.]*

The Resident Doctor arrived in ACCC at around 3 pm. There were nine patients waiting for IV chemotherapy that afternoon including the patient involved in this medication incident. At around 3:05 pm, while the Resident Doctor was preparing to give IV chemotherapy, she was informed by nursing staff that a patient was waiting for IT chemotherapy. As the laboratory closing time for receiving a cerebrospinal fluid (CSF) specimen was 3:30 pm, she decided to proceed with the IT chemotherapy administration.

The Enrolled Nurse delivered the trolley with the two chemotherapy drugs to the patient's bedside. The Resident Doctor reviewed the patient's medical record, obtained written consent from the patient for IT chemotherapy and prepared her for LP. After checking the prescription sheet with the Enrolled Nurse, the Resident Doctor proceeded to prepare the two chemotherapy drugs. The Resident Doctor and the Enrolled Nurse were not aware of the two different routes of administration prescribed for vincristine and cytarabine, i.e. IV for the former and IT for the latter.

Assisted by the Enrolled Nurse, the Resident Doctor dissolved the cytarabine (100mg powder) with 2 ml sterile water and aspirated 1 ml (i.e. 50mg) into a syringe using aseptic technique. The Resident Doctor had concern about the sterility of the pre-filled syringe of vincristine because IT injection via a spinal needle must be performed under strict aseptic technique. In view of the above concern, the Resident Doctor reviewed the previous prescription sheet and noted that the same drugs had been used in the previous procedure. The Resident Doctor, assisted by the Enrolled Nurse, then used a sterile syringe to aspirate the vincristine from the pre-filled syringe for subsequent IT injection (Plate 4).

The Resident Doctor performed LP using a spinal needle, obtained a sample of CSF for laboratory study and then injected the two chemotherapy drugs, i.e. cytarabine (50mg in 1ml) and vincristine (2mg in 2ml), intrathecally via the spinal needle.

The Resident Doctor signed the given drugs on the prescription sheet at about 3:35 pm and made an entry into the Clinical Management System record at 3:47 pm.

She advised the patient to rest for one hour before going home. The patient left ACCC later.

The Resident Doctor concerned was on leave afterward.

4.4 Recognition of the event and management

The patient attended the Department of Accident and Emergency of PWH the following morning (16 June) because of fever, neck pain, back pain, headache, pain and weakness of lower limbs. She was admitted to DOC for in-patient treatment. The initial diagnosis was infective meningitis and the patient was managed accordingly. Her condition deteriorated after admission.

The error was suspected in the evening of 18 June when the Resident Doctor returned to PWH and learned from another doctor that the patient had developed symptoms suggestive of meningitis. At that time she realized that the patient might have received IT administration of vincristine.

A Professor of DOC was informed of the possibility that the patient had received IT administration of vincristine by telephone the same evening. In his judgment there was no effective therapy to reverse effects of IT administration of vincristine and he decided to review the patient the following morning and to check the medication records to determine whether IT administration of vincristine had indeed been given.

On 19 June, the Professor assessed the patient and documented in the medical record that her condition might be due to toxic effects of chemotherapy. He set up a meeting with the Head of DOC, and the meeting took place in the morning of 20 June.

On 20 June, review of the medication record and interviews with involved personnel confirmed that IT administration of vincristine had been given inadvertently. The patient's family was informed of the error at around 7 pm.

Full supportive care was continued. On 21 June, the Department of Neurosurgery instituted measures to flush the CSF by making a burr hole and external lumbar drainage. It was recognized that this procedure would have a low chance of benefit.

The patient died on 7 July. The death was reported to the Coroner.

4.5 Subsequent changes in drug administration procedures

DOC issued two memoranda on 25 June and 14 July respectively to announce additional safety measures for prescription, preparation and administration of IT chemotherapy and IV vincristine chemotherapy (Table 3).

Table 3 - Summary of additional safety procedures announced on 25 June and 14 July by DOC of PWH

	IT chemotherapy	IV chemotherapy
Staff competency	<ul style="list-style-type: none"> House officers should not perform IT chemotherapy Medical officers under training need to: <ul style="list-style-type: none"> observe IT injection of chemotherapy performed by a specialist/fellow in Medical Oncology be aware of the standard operating procedures perform IT injection of chemotherapy in at least 3 patients under supervision of a specialist / fellow in Medical Oncology The above should be documented, signed & countersigned on the form "Department Training Record in IT Administration of Chemotherapy" before the medical officer can perform the procedure independently 	<ul style="list-style-type: none"> House officers & medical officers under training need to: <ul style="list-style-type: none"> observe IV injection of chemotherapy performed by a specialist/fellow in Medical Oncology be aware of the standard operating procedures, including management of extravasation perform IV injection of chemotherapy in at least 3 patients under supervision of a specialist/fellow in Medical Oncology The above should be documented, signed & countersigned on the form "Department Training Record in IV Administration of Chemotherapy" before the individual can perform the procedure independently
Prescription	<ul style="list-style-type: none"> Use a new prescription sheet specific for IT chemotherapy Double check with a 2nd medical staff 	
Dispensing by pharmacy	<ul style="list-style-type: none"> IT drug items must be supplied in their original form & delivered in a separate container or plastic bag 	<ul style="list-style-type: none"> Prepare Vincristine in a small volume IV bag with 50ml normal saline Place warning labels "For Intravenous Use Only. Fatal if Administered by Other Routes" on the Vincristine IV bag & the container or plastic bag holding the drug
Administration	<ul style="list-style-type: none"> Administer at different times and/or in a different location if a patient also needs IV chemotherapy on the same day Preparation must be carried out at the bed-side from the original form by the medical officer who is to perform the administration Cross-checking of identity of the intended recipient (patient), drug name, dosage, frequency & route of administration, & signing on the prescription sheet by 2 qualified persons (doctor or nurse) 	<ul style="list-style-type: none"> Vincristine to be given as a short IV infusion over 5 minutes

5. Training in medical oncology

Salient points:

- Patient-centred teaching of medical oncology trainees on the wards and outpatient clinics of DOC at PWH provides multiple opportunities to learn about the toxicities of chemotherapy drugs given in recommended dosages and by usual routes of administration, including the neurotoxicity of vincristine
- Patient-centred teaching might or might not lead to discussion of the probable outcome of medication errors such as inadvertent overdosage of chemotherapy, or administration of vincristine or other drugs by the IT route
- Apart from Wednesday afternoons which were dedicated to postgraduate education, there was no regular protected time for medical oncology trainees to attend formal structured educational programs
- Each trainee was assigned a trainer who conducted the training coordinated by the Program Director designated by the Hong Kong College of Physicians according to the Training Guidelines under the Medical Oncology Board
- Medical oncology trainees are expected to complement their hospital-based training through self-study, and texts and other materials are recommended for self-study; however, there were no mechanisms to ensure coverage of items such as knowledge that inadvertent IT administration of vincristine is likely to be fatal.
- A trainer or specialist would normally demonstrate the IT chemotherapy procedure personally to the new medical oncology trainees, and the trainees would then be allowed to perform IT chemotherapy administration under supervision and subsequently independently; however, there were no formal mechanisms to ensure competence of medical oncology trainees before allowing them to perform IT chemotherapy administration independently
- There were no formal mechanisms to ensure that nursing and other staff working in DOC/ACCC, or in the Pharmacy, had adequate background knowledge about cancer chemotherapy and were kept abreast of updated local and overseas information

5.1. Training of doctors

The medical oncology training program of the DOC at PWH follows the guidelines of the Hong Kong College of Physicians. The Panel is convinced that the training program provides excellent patient-centred teaching on the wards and in ACCC, but it appears that most learning is either a by-product of clinical service or occurs through self-study. Internationally, medical oncology training programs have evolved to allow a balance between education and service, and include formal courses and a detailed syllabus to ensure complete coverage of all important information that should be known by medical oncologists. This does not appear to be a feature of the PWH medical oncology training program.

The Panel interviewed the Resident Doctor involved and another trainee and asked specific questions about the training program. The trainees indicated that they had educational events on Wednesday afternoons including a pathology review and a journal club. Topics were selected by staff or trainees on an ad-hoc basis. When asked how they learned about toxic side-effects of chemotherapy, they indicated that most learning was gained by observing patients seen on the wards or in ACCC, or through self-study. Apart from the Wednesday afternoon sessions, they described no regular protected time for education/training. They were unable to attend a formal course organized by Clinical Oncology on Saturday mornings because of conflicting ward rounds, but were encouraged and supported by DOC to attend local and international meetings. They both indicated that they were aware that vincristine was a neurotoxic drug. However, prior to the incident, they were not aware that vincristine given intrathecally was usually fatal.

The Panel also interviewed senior staff of DOC. They indicated that all trainees were expected to review appropriate texts related to medical oncology that would certainly include information about

toxicity of chemotherapy, and possibly that vincristine must not be given intrathecally. Senior staff did advise the trainees on appropriate sources of reference material. Each trainee has been assigned a trainer and the trainee is evaluated at least every 6 months by the trainer; this evaluation includes a review of their log-book which documents the procedures that they have undertaken.

In DOC, each Wednesday afternoon was dedicated to postgraduate education. This was an approved continuing medical education (CME) activity of the Hong Kong College of Physicians and attendance was documented by personal signatures. However, there appeared to be neither formal mechanism to ensure competence of medical oncology trainees before allowing them to administer IT chemotherapy independently nor structured didactic training for doctors on drug checking and toxicity of chemotherapy.

5.2 Training of nurses and pharmacists

The Panel asked specific questions about in-service and continuing education for nurses working in ACCC and for pharmacists involved in preparation of chemotherapy. The workload in both departments is very busy such that the staff often work overtime. There are no formal structured educational events for nurses or pharmacists.

Within ACCC (not including staff in DOC working on inpatient wards) two Nurse Specialists and three of the Registered Nurses who have received training in advanced oncology nursing and chemotherapy administration are familiar with the properties of chemotherapy drugs. In the Pharmacy there is a monthly department meeting to discuss operational and management issues and there is a monthly newsletter and ad hoc e-mails, which disseminate information about new formulary drugs and drug safety.

Members of both disciplines indicated that they, and some of their colleagues, would like to have more educational events, but it was difficult or impossible to schedule such events within the normal working day. They were encouraged to attend relevant external courses.

6. HA-wide policy

Salient points:

- There was a HA guideline specifying referral of patients with leukaemia to designated secondary/tertiary cancer centres
- There was a HA guideline on drug administration procedures and practice which recommended the principle of '3 Checks and 5 Rights'
- There was no specific HA-wide policy for safe administration of chemotherapy
- There was specific HA policy for training, assurance of competence and deployment of pharmacy staff for preparation of chemotherapy, but not for medical staff and nursing staff
- Practices designed to ensure safe administration of chemotherapy varied among clusters
- HA issued an interim guideline in July 2007 on IV administration of vincristine and measures to prevent inadvertent IT administration of vincristine

6.1 Management of patients with leukaemia in designated hospitals

A HA guideline on the management of leukaemia and other haematological conditions had been issued by the HA Co-ordinating Committee in Internal Medicine in July 2001. It was specified in the guideline that all patients with leukaemia, irrespective of age, should be referred to secondary or

tertiary Cancer Centres for a decision about the treatment to be offered (Table 4).

Table 4 - Hospitals designated for management of patients with leukaemia in each HA cluster

Cluster	Designated hospital
Hong Kong East Cluster (HKEC)	Pamela Youde Nethersole Eastern Hospital (PYNEH)
Hong Kong West Cluster (HKWC)	Queen Mary Hospital (QMH)
Kowloon Central Cluster (KCC)	Queen Elizabeth Hospital (QEH)
Kowloon East Cluster (KEC)	United Christian Hospital (UCH) Tseung Kwan O Hospital (TKOH)
Kowloon West Cluster (KWC)	Princess Margaret Hospital (PMH)
New Territory East Cluster (NTEC)	Prince of Wales Hospital (PWH)
New Territory West Cluster (NTWC)	Tuen Mun Hospital (TMH)
Total: 8	

6.2 Precautions on administration of vincristine / chemotherapy / drugs

There was no specific HA-wide policy in place for safe administration of vincristine (in particular) or chemotherapy (in general) prior to the incident. There is a HA-wide policy on administration of drugs in general, which is described in the document: **Report on Drug Administration Procedures and Practices in Public Hospitals (2005)**. The document stipulates under Recommendations 4.99 – 4.113 that the principle of ‘3 Checks and 5 Rights’ should be followed to ensure that the right drug at the right dose is given via the right route at the right time to the right patient. Also, that when a high risk IV medication is prescribed, the prescription order must be independently checked by 2 nurses to ensure that the order has been correctly interpreted and the drug, dose calculation, preparation, route and mode of administration are accurate. However, these recommendations are addressed to nurses, and doctors are not mentioned explicitly.

There are local policies in some clusters/hospitals. Some hospitals have detailed written policies and procedures for safe handling and administration of cytotoxic drugs, while others do not.

6.3 Training, assessment and deployment of staff involved in preparation and administration of chemotherapy

There is a specific HA-wide policy in place for pharmacy staff in that only those who are trained are allowed to prepare cytotoxic preparations. Periodic validation of technique is required for pharmacy staff in preparing cytotoxic preparations. This is stipulated in the **Practice Standard for Pharmaceutical Services (2001)**.

There is no specific HA-wide system in place for training, assurance of competence and deployment of medical and nursing personnel involved in administration of chemotherapy. There are local policies in some, but not all clusters/hospitals.

Regarding the role of Enrolled Nurses, it is stipulated under Recommendations 4.94 of the **Report on Drug Administration Procedures and Practices in public hospitals (2005)** that “Enrolled Nurses should work within their qualification and training. In normal circumstances, they can administer medications, when delegated this duty by Registered Nurses. In the case of the extended and expanded role of the Enrolled Nurse, an enabling course or clear guidelines should be provided”.

6.4 New initiatives on safe management of IT chemotherapy

A task group was set up in July 2007 under the Medication Safety Committee of the HA Head Office to develop a concise and comprehensive guideline for the safe management of IT chemotherapy in HA. An interim guideline on IV administration of vincristine and measures to prevent inadvertent administration by the IT route was issued in July 2007 (Appendix 4). A full set of guidelines for the management and safe administration of IT chemotherapy will be developed.

7. Analysis

The evidence presented to the Panel suggested that system factors, education factors and human error contributed to the medication incident.

7.1 System factors

1. HA had a policy for the safe administration of drugs in general but there was no specific guidance on:
 - a. safe administration of IV vincristine and IT chemotherapy;
 - b. structured training, assurance of competence and appropriate deployment of medical and nursing staff on administration of chemotherapy.
2. PWH had a policy for the safe administration of chemotherapy and specific guidelines for administration of IV vincristine and IT chemotherapy. However, these guidelines did not mandate separate prescription, delivery, storage, checking and administration of IV vincristine and IT chemotherapy. In particular, IV vincristine and IT chemotherapy could be placed together on a trolley.
3. The warning on the dispensing drug label for vincristine needed to be highlighted more prominently.
4. There was no specific DOC/ACCC policy for medical staff to perform a formal checking procedure with a second qualified person to ensure the correct administration of IT chemotherapy.

7.2 Education factors

- 1 The medical oncology training program at PWH follows the guidelines of the Hong Kong College of Physicians and it provides excellent bedside teaching. However, there was no regular protected time for medical oncology trainees to attend formal structured educational programs, and no formal mechanism to ensure that they acquired the information that inadvertent IT administration of vincristine is likely to be fatal.
- 2 Trainees in medical oncology were assigned a trainer, and were required to maintain a log-book documenting procedures that they had undertaken, that was signed by their trainer. However, there was no formal mechanism to ensure competence of trainees before allowing them to administer IT chemotherapy independently.
- 3 Although the nursing staff in ACCC and pharmacists in the Pharmacy have all received appropriate professional training, there was no policy to provide specialized oncology/chemotherapy training to all nursing staff in ACCC, or to pharmacists involved in preparation of cytotoxic drugs.
- 4 IT procedures were restricted to trained medical staff and not allowed to be carried out by junior doctors but there was no formal mechanism to ensure that staff working in DOC/ACCC, or in the Pharmacy, had adequate background knowledge about chemotherapy or were kept abreast of updated local and overseas information.

7.3 Human error

- 1 The Resident Doctor and the Enrolled Nurse did not comply with the basic principles of safe medication administration and they failed to check the route of administration prescribed on the prescription sheet for vincristine
- 2 The Resident Doctor and the Enrolled Nurse were not aware of the following:
 - i the warning on the dispensing label on the overwrap and the pre-filled syringe of vincristine, i.e. "For IV ONLY"
 - ii the implication of dispensing vincristine in a pre-filled syringe, i.e. for IV use.
- 3 The doctor who administered the vincristine was described by senior staff as responsible, intelligent, well-liked and competent. There was no evidence that she had committed any serious medical errors in the past.

8. Conclusions and Recommendations

8.1 Conclusions

The causes of this unfortunate incident are multiple, but can be broadly separated into 3 components:

- 1 "System factors" including the delivery to the ambulatory care unit of intravenous vincristine and intrathecal cytarabine together, to be administered at the same time and in the same location, and with imperfect labelling; also inadequate checking of the medication and route of administration.
- 2 "Education factors" leading to insufficient awareness that intrathecal administration of vincristine is likely to be fatal, that similar incidents have occurred elsewhere and that there are international guidelines to prevent them.
- 3 "Human error" that was related to the above factors, and such that failure to follow existing guidelines led to a fatal incident.

8.2 Recommendations

The following recommendations are made to enhance the systems in place in the hospital and HA and to minimize the possibility of human error.

8.2.1 To improve the System

Establish standard operating procedures in all public hospitals which administer IT chemotherapy that are based on international guidelines. These should include:

- 1 Only specially trained and designated oncology staff should prescribe, prepare dispense and administer cytotoxic medication.
- 2 Medical staff should use separate prescription sheets for prescription of IV vincristine and IT chemotherapy.
- 3 The clinician administering IT chemotherapy must be familiar with the patient and with the chemotherapy protocol.
- 4 Medical staff must use a formal checking procedure, involving a nurse who has received training about cancer chemotherapy (or another doctor), to ensure that the right drug is given at the right dose, by the right route, at the right time and to the right patient.
- 5 Specifically designated containers must be used both for transportation of IT drugs from the Pharmacy and for storage on the ward or ACCC.

- 6 All IT drugs must be packaged separately and clearly labelled on the container(s) "For Intrathecal Use".
- 7 IT chemotherapy must only be administered in an area where no other cytotoxic drugs are available.
- 8 IT drugs must be administered at a different time from other systemically administered drugs.
- 9 Vincristine should be prepared in a small-volume IV bag when administered to adults and older children. For small children dilution in a 10 to 20ml syringe is appropriate.
- 10 Vincristine should be clearly labelled on the bag and on the outer container "For Intravenous Use Only – Fatal If Given by Other Routes". Negative labels, such as 'Not for Intrathecal Use' must not be used.

The following is optional:

- 11 Patients or their families may be involved in the checking process.

8.2.2 To improve Education

The medical oncology training program at DOC of PWH follows the guidelines of the Hong Kong College of Physicians. It provides excellent bedside teaching but most learning is largely a by-product of clinical service. Discussion of inappropriate treatments (e.g. administration of IT vincristine) may not take place during patient-centred teaching. Internationally, medical oncology training programs have evolved to allow a balance between education and service, and to include a syllabus to ensure coverage of all important information that should be known by medical oncologists. We suggest that the medical oncology training programs at public hospitals be modified in line with international trends. Important modifications will be:

- 1 Protected time when trainees have no clinical responsibilities. (e.g. one morning per week) to allow formal teaching that should include, amongst others, courses covering -
 - i natural history and management of all common malignancies;
 - ii properties of anti-cancer drugs including their modes of action, toxicities, mechanism of resistance etc;
- 2 Rotations when trainees can concentrate on particular types of malignancies such as haematological versus solid tumours. This will allow trainees to undertake procedures (including systemic treatment of leukaemia) during a period when they can become familiar with the relevant patients and protocols.

For efficiency, we suggest that PWH explores the possibility of common formal teaching of medical oncologists with the other Hong Kong programs, and where appropriate, with programs in clinical oncology.

Medication incidents such as this one are less likely to occur if all members of the clinical team are educated to recognize potential hazards of the use of anti-cancer therapy. We therefore recommend regular in-service education (e.g. monthly formal presentations within protected time) for pharmacists and nurses working in the field of oncology. We believe that providing a minimum of one hour per month of formal protected educational time for both pharmacists and nurses is possible and should be given the highest priority. Such in-service education should emphasize knowledge about systemic treatment for cancer and should highlight international guidelines that are designed to prevent potential causes of medication error. We also encourage nurses and pharmacists to continue their education through relevant courses and other means.

Special Investigation Panel on the Medication Incident

Membership

Professor Ian Tannock	Professor of Medical Oncology at Princess Margaret Hospital and the University of Toronto	Chairman
Professor Grace Tang	President, Hong Kong Academy of Medicine	
Dr P Y Leung	Director (Quality & Safety), HA	

Terms of reference

1. To investigate circumstances surrounding the Medication Incident; and
2. To make recommendations to prevent recurrence of similar incidents across HA.

Objectives

Pursuant to the above terms of reference, the Panel will adhere to the following objectives:

1. To obtain relevant evidence, whether documentary or oral, and, for this purpose, to interview such persons (“Relevant Persons”) as the Panel may consider appropriate; and
2. To prepare a report to the Chief Executive of HA.

Guiding Principles

The Panel will be guided by the following guiding principles:

- ☐ Nature of the investigation – This is an internal investigation. The purpose of the investigation is to establish a factual account of the Medication Incident and to ascertain whether there is a HA-wide system on the administration of vincristine. The investigation may discover acts, which should not have been done and/or omissions and the Panel may report such findings. Notwithstanding this, the investigation is not any form of disciplinary procedure.
- ☐ Confidentiality – The Panel will observe the need to respect confidentiality of information that comes into its possession during the course of its work.
- ☐ Impartiality – The Panel will conduct itself in a way that is independent, fair and impartial.
- ☐ Effectiveness – The Panel will endeavour to proceed with its work as efficiently as possible in the circumstances. The Panel will set its own timetable and deadlines and will do all that it reasonably can to overcome delays, which lie outside its direct control.
- ☐ Accessibility – The Panel will conduct itself in a non-adversarial manner in all its dealings with the Relevant Persons and will operate as informally as circumstances permit. This is an internal investigation only. All interviews are conducted for the purposes of fact finding. As such no legal representation is required or permitted.
- ☐ Openness – The Panel will conduct itself in accordance with the processes and methods of working

as set out in this document.

- ❑ Accountability – The Panel will hold itself accountable to the Chief Executive of HA for adherence to the above terms of reference.

Procedures

The Panel may adopt such procedures as it may consider fair and efficient to conduct the investigation. Without limiting the procedures, which the Panel may adopt, the Panel may consider the following:

- ❑ Documents – The Panel will commence the investigation by obtaining relevant information/documents from the Relevant Persons. The Panel may request more information/documents if necessary.
- ❑ Questionnaires – The Panel will issue standard form questionnaires to the Relevant Persons. Each Relevant Person will only be required to answer the questions in which he/she is able to assist the Panel. Following a review of the initial questionnaires, the Panel may deem it necessary to issue additional questionnaires before proceeding to interviews.
- ❑ Interviews – Following the completion of written questionnaires, the Panel will arrange for interviews to take place. The Panel will request interviews with such Relevant Persons from whom it considers appropriate to hear oral evidence. Any Relevant Person who is not called for interview but who has been included in the process, by virtue of completing a questionnaire, can request an interview with the Panel. The Panel will only interview those Relevant Persons that have completed a questionnaire. These interviews will allow the Relevant Persons and/or the Panel to address any issues that were not covered by the questionnaires to provide more detail to their written answers. The interviews are non-adversarial and will focus on fact finding. A Relevant Person is not allowed to be accompanied by a lawyer or any third person. Each Relevant Person will be interviewed individually and in privacy. Tape recording of each interview will be made and provided to the respective Relevant Persons upon request.

The Panel may obtain evidence by the above methods from all appropriate sources.

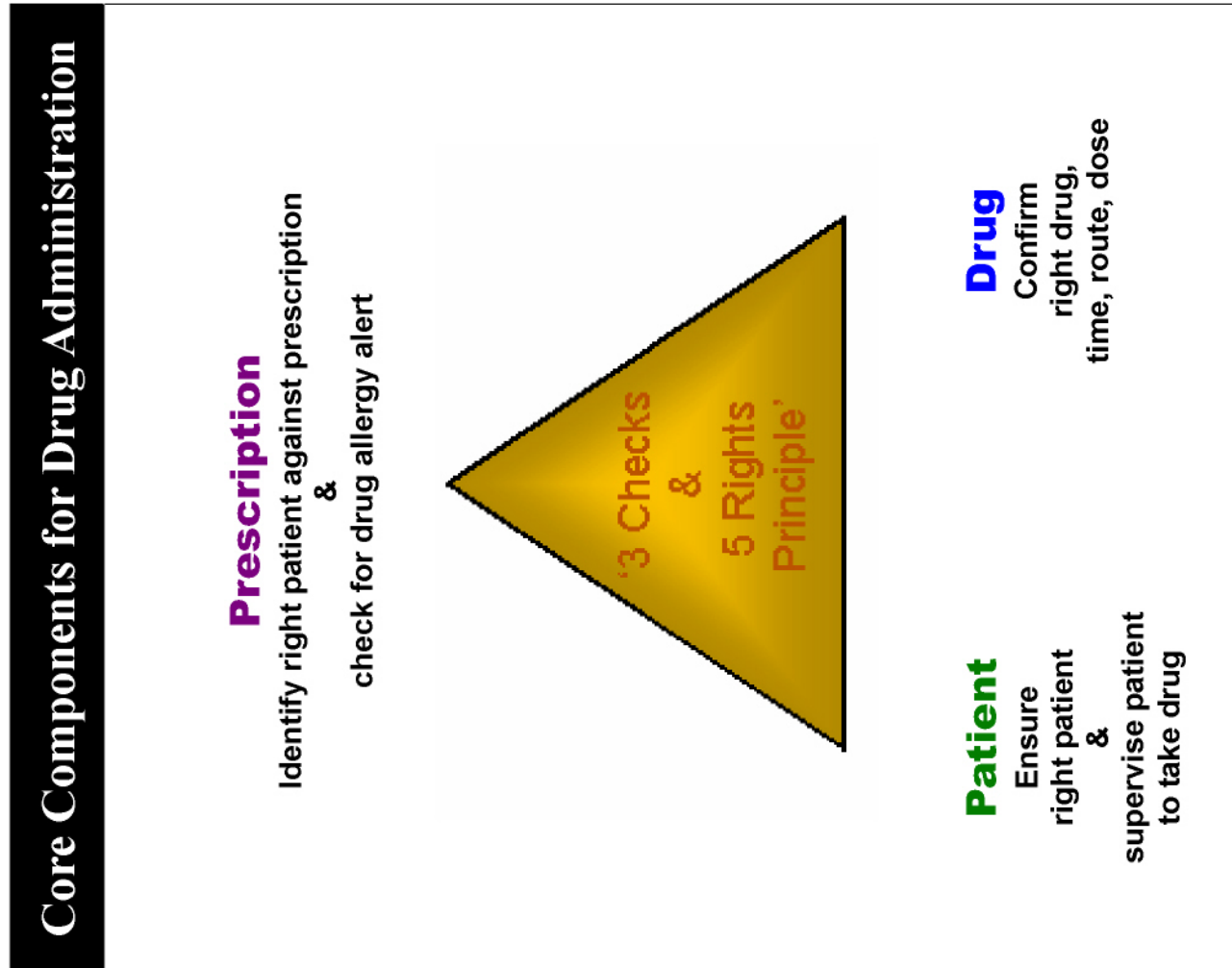
After the closure of the interview stage, each Relevant Person will be provided with a summary of his/her evidence for verification of its accuracy. The Panel will advise the Relevant Persons that any comments on the summaries of their evidence must be made in writing to the Panel within 3 days of receipt of the summaries otherwise the summaries will be taken as verified by these Relevant Persons as accurate.

After the summaries of the evidence of these Relevant Persons have been verified, the Panel will prepare a report as required in the above objectives and submit it to the Chief Executive of HA.

List of people who gave verbal and/or written evidence to the Panel

In addition to the two staff directly involved in the incident, the following people also gave verbal and/or written evidence to the Panel.

Name	Post	Verbal Evidence	Written Evidence
1. Prof Chan	Chief of Service, Department of Clinical Oncology, PWH	✓	✓
2. Ms Chan	Pharmacist, Pharmacy, PWH	✓	✓
3. Dr Chan	Resident, Department of Clinical Oncology , PWH	✓	✓
4. Dr Chiu	Cluster Chief Executive, KWC		✓
5. Dr Fung	Cluster Chief Executive, NTEC		✓
6. Dr Hung	Cluster Chief Executive, KCC		✓
7. Dr Lai	Cluster Chief Executive, HKWC		✓
8. Ms Lee	Nurse Specialist, Department of Clinical Oncology, PWH	✓	✓
9. Mr Lee	Chief Pharmacy, Chief Pharmacy Office		✓
10. Dr Lei	Director, ACCC, PWH	✓	✓
11. Ms Leung	Registered Nurse, Department of Clinical Oncology, PWH	✓	✓
12. Ms Leung	Enrolled Nurse, Department of Clinical Oncology, PWH		✓
13. Dr Li	Chief of Service, Department of Paediatrics, PWH	✓	✓
14. Dr Lo	Cluster Chief Executive, NTWC		✓
15. Dr Lui	Service Director (RM & QA) , PWH	✓	✓
16. Dr Luk	Cluster Chief Executive, KEC		✓
17. Prof Mok	Professor, Department of Clinical Oncology, PWH	✓	✓
18. Mr Ng	Pharmacist, Pharmacy, PWH	✓	✓
19. Dr Yam	Cluster Chief Executive, HKEC		✓
Total No.		10	19



Revised '3 Checks & 5 Rights' Procedures		
1st check	Check all MAR forms of patient to identify the drug(s) to be given during the drug round. (ensure patient is available)	Right time
2nd check	Check drug out from the drug cupboard or drug trolley. Check the drug against MAR form to ensure right drug (check for drug allergy alert), dose, route, time as well as patient label on individual dispensed drug (if information available). Also check the expiry date of drug.	Right patient Right drug Right route Right dose Right time
3rd check	Check patient's name and ID no. on bracelet against MAR form to ensure right patient before giving drugs.	Right patient

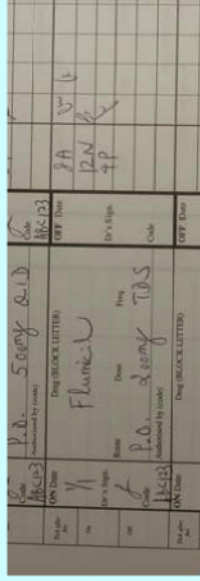
Drug Administration '3 Checks and 5 Rights' Procedures

(revised 1 March 2006)

1st CHECK (right time)

Check all MAR forms of patient for drug to be given during drug round.

(ensure patient is available)



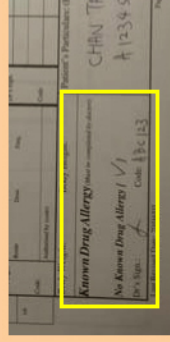
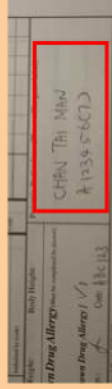
Check if all pages of MAR belong to same patient

Look for drug(s) to be given (check frequency, time & route)

Ensure patient is available & is able to take drug

2nd CHECK (right patient, drug, route, dose, time)

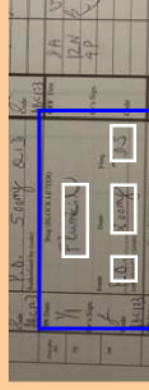
Check drug out from the drug cupboard / trolley.



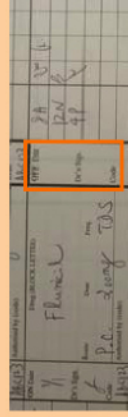
① Check patient identity between drug label & MAR
② Check patient's allergy status

Check drug against MAR form(s) to ensure right drug (including drug allergy), dose, route, time as well as patient label on individual dispensed drug package (if information available).

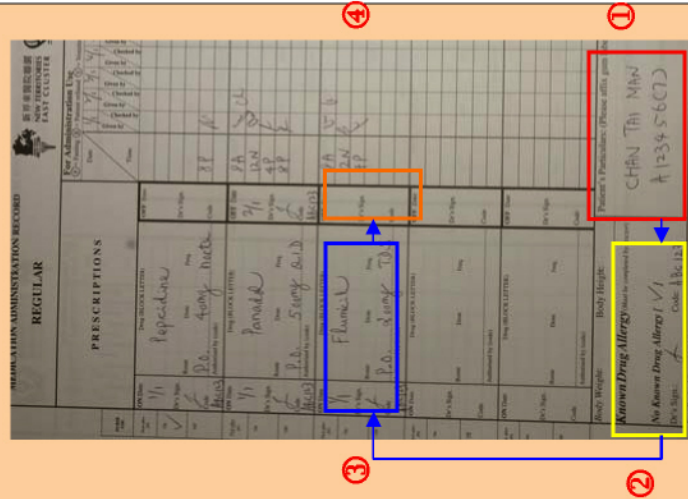
(check expiry date of drug)



③ Check drug name, route, dose & frequency + expiry date of drug(s) to be given

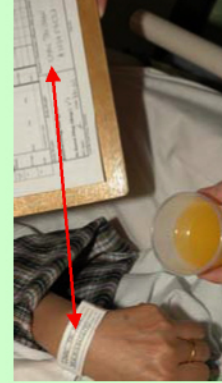


④ Check 'OFF' column



3rd CHECK (right patient)

Check patient's name & ID no. on bracelet against MAR to ensure right patient before giving drugs.



Ask patient to tell his/her name

Check name & ID no. of MAR against bracelet

Supervise patient to take drug(s)

Sign on MAR accordingly



(Interim Guideline)

Intravenous Administration of Vincristine and measures to prevent inadvertent administration by intrathecal route

Subject officers: HAHO Q&S Division. Q&RM Department - CM(Q&RM),
& HAHO, Cluster Service, CPO Division - CP

w.e.f. 1 August 2007

In response to the fatal medication incident due to the inadvertent intrathecal administration of vincristine in the Hospital Authority, the Medication Safety Committee in conjunction with HAHO Q&S Division has convened a task group to develop a set of guidelines for the management and safe administration of intrathecal chemotherapy with a view to reduce the risk of such error to zero (zero tolerance). While a full set of guideline on the “Safe Intrathecal Chemotherapy” will be developed, as an interim measure, the following recommendations on the intravenous administration of vincristine and measure to prevent inadvertent intrathecal administration of Vincristine have been endorsed for immediate implementation.

(1) Prescriptions (Medical staff)

All intrathecal chemotherapy should be prescribed in a separate prescription form.

(It can be a designated Medication Administration Form (MAR) purposefully designed for intrathecal drug only. For out-patient setting where CMS MOE is used to prescribe medications, the printing function of CMS MOE will be enhanced to print intra-thecl drug on a separate prescription sheet in the future).

(2) Dispensing (Pharmacy / staff preparing the medication)

(a) All intravenous doses of vinca alkaloids to be diluted in at least 50ml infusion minibag for adults and 10-20ml syringe for paediatrics to distinguish them from intrathecal drugs.

(b) All dispensed vinca alkaloids must be labeled with an eye catching warning message “For intravenous use only. Fatal if given by other routes”

In addition:




- (c) All dispensed intrathecal drugs must be labeled with a warning message "For Intrathecal Use Only".
- (d) All dispensed intrathecal chemotherapy must be dispatched separately in a designated container or in a sealed envelope / bag (marked "Intrathecal drug").



(3) Administration (medical / nursing staff)

- (a) Parenteral drug(s) and intrathecal drug must be administered as separate procedures, i.e. separated in time in setting up and initiating the administration.
- (b) Appropriate trained staff to administer chemotherapy
 - For intravenous drugs: by staff (medical or nursing) trained for administering of chemotherapy drugs
 - For intrathecal drug: by medical staff trained for intrathecal drug injection
- (c) Immediately prior to drug administration:
 - The staff responsible for the drug administration must verify the 5 "Rights" (Right patient, right time, right drug, right dose and right route) against the prescription.
 - A second trained (medical or nursing) staff is required to independently verify the patient identification and drug checking process.
 - Both staff must sign the medication administration (MAR) chart
(for intrathecal drug - preferably in a purposefully designed MAR form for intrathecal drug with a checkbox for each "Right" requiring verification).
- (d) Monitoring: Procedures should be in place for monitoring, preventing and treating extravasation of vinca alkaloids diluted in mini-bags.

26 July 2007

Plates

<p>Plate 1</p>	<p>A reconstruction of the labels affixed to the pre-filled syringe of vincristine and the overwrap</p>	
<p>Plate 2</p>	<p>A reconstruction of the label affixed to the cytarabine container</p>	
<p>Plate 3</p>	<p>A reconstruction of the two chemotherapy drugs inside a transparent plastic bag</p>	

<p>Plate 4</p>	<p>A reconstruction of the two chemotherapy drugs on the trolley</p>	 <p>A stainless steel medical trolley is shown, loaded with various medical supplies. On the top shelf, there is a white bowl containing a black object, a stack of white papers or bags, and a box labeled 'Ansell'. The lower shelves are filled with numerous boxes and bottles of chemotherapy drugs, including a large white bottle and several smaller boxes. The trolley is positioned next to a bed with a colorful patterned blanket.</p>
<p>Plate 5</p>	<p>A reconstruction of the aspiration of vincristine from the pre-filled syringe to a sterile syringe</p>	 <p>A close-up photograph shows a person's hands performing a procedure. One hand holds a pre-filled syringe, while the other hand uses a sterile syringe to aspirate liquid from it. The background is a plain, light-colored wall.</p>