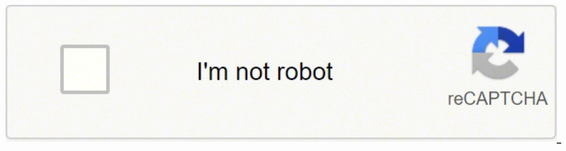

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Cytotoxic drug reconstitution pdf

Responsibilities of Manufacturers of Cytotoxic Drugs

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Standards Committee, International Society of Oncology Pharmacy Practitioners (ISOPP)

Abstract

In 2007, the International Society of Oncology Pharmacy Practitioners (ISOPP) published its Standards of Practice for the Safe Handling of Cytotoxic Drugs, which places a number of responsibilities on the manufacturers of cytotoxic agents. This includes the provision of contamination-free products. In particular, ISOPP would like manufacturers to provide information on the procedures used to limit contamination on the outside of cytotoxic products and documentation on the actual levels of contamination likely to be present. Another area of concern is the primary container and packaging of cytotoxic drug products. This must be produced to minimise the risk of breakage, and must be able to prevent leakage or spillage if breakage does occur. In addition, ISOPP asks manufacturers to label their cytotoxic products with a prominent and unique warning sign to clearly identify the contents as being cytotoxic in nature. ISOPP would like to see manufacturers work together with oncology pharmacists towards achieving best practice.

Keywords

Cytotoxic, contamination, drug manufacturers, packaging, labelling, transportation, stability

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In 2007, the International Society of Oncology Pharmacy Practitioners (ISOPP) published its Standards of Practice for the Safe Handling of Cytotoxic Drugs.[1] This comprehensive document places a number of responsibilities on the manufacturers of cytotoxic agents, including measures to maximise safe handling and to limit chemical contamination. Over the years, many amendments have been made to the presentation and packaging of cytotoxics to improve containment. However, more must be done, particularly in relation to the external chemical contamination of drug products. Other areas of concern include the labelling and transportation of cytotoxics and the completeness of information made available by manufacturers. This article addresses the main areas where the initiative and co-operation of the pharmaceutical industry is required.

Primary Containers

Manufacturers must ensure that primary containers of cytotoxic drugs (e.g. vials) are designed to minimise the risk of leakage or breakage by using leak-proof and break-resistant materials. These include vials manufactured from an unbreakable plastic material or glass vials overwrapped in plastic to prevent contamination in the event of breakage of the glass. A glass vial contained within an outer break-resistant or tough/strong plastic container for each unit is another suitable option.

This consideration applies to all dosage forms, including oral and topical formulations. Capsules may represent a special risk, where breakage of the container may result in release of the contents of the capsule.

Packaging

All cytotoxic products for transportation from the manufacturer must be protected with high-impact-resistant moulded foam or other suitable packaging material to help prevent damage to the primary containers. The outer packaging must also ensure containment of cytotoxic spillage in the event of breakage.

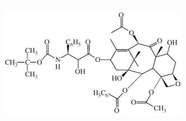
Transportation

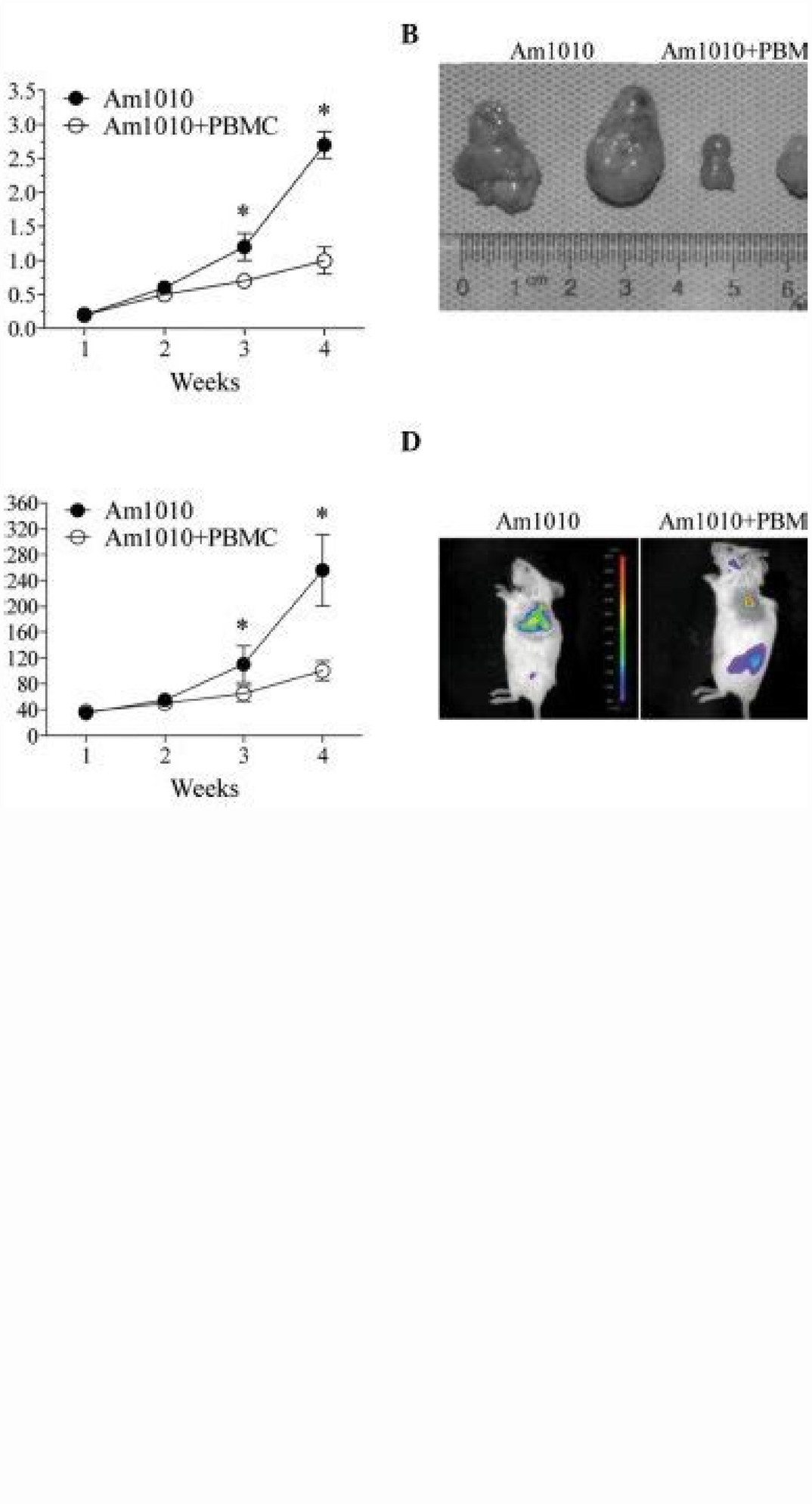
Manufacturers must ensure that all distributors of their products are aware of, and comply with, all packaging and transportation requirements until products are received at their final destination.

Labelling

Cytotoxic drugs must be easily identifiable by all personnel involved in their handling. The outer packaging of containers must display clear warning labels stating that the goods are cytotoxic in nature. Ideally, there should be a universal symbol adopted globally for cytotoxic agents; the symbol should be unique and instantly recognisable, and should not require workers to have language skills to recognise the hazard. Most countries have some recognised symbol representing cytotoxic agents. The symbol varies among countries, but in many cases it is purple and often contains a diagramatic representation of a cell in telophase. It may say 'Danger/Caution Cytotoxic', or may contain an exclamation mark. Whatever warning sign is attached, it should be clear and easily recognisable.

In many countries it is not mandatory for manufacturers to identify cytotoxic agents in this way. ISOPP strongly urges manufacturers to





British Journal of Haematology, 1980, 45, 223–231.

Haematological Reconstitution after Autografting for Chronic Granulocytic Leukaemia in Transformation: the Influence of Previous Splenectomy

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SUMMARY. Peripheral blood values and bone marrow appearances were monitored in eight patients treated for chronic granulocytic leukaemia in transformation by cytotoxic drugs with or without total body irradiation followed by autografting with cryopreserved-thawed peripheral blood nucleated cells. One of the patients was 'autografted' on two occasions. Five patients had been splenectomized early in the first chronic phase and the other three patients had their spleens intact. Recovery of peripheral blood values was more rapid in the splenectomized than in the non-splenectomized patients. CFUc were present in the circulation immediately after autografting in each case but subsequently the pattern of CFUc changes differed between patients. The bone marrow was hypocellular at the time of autografting but the rate at which it returned to a typical chronic phase picture varied. Peripheral blood nucleated cells collected at the time of diagnosis include stem cells with the capacity to repopulate the marrow after 'ablative' therapy for transformation. Elective splenectomy in the chronic phase may promote more rapid recovery of peripheral blood values but its long-term importance is unknown.

In 1978 we reported the use of cryopreserved-reconstituted bone marrow cells as an autograft to speed the haematological recovery of a patient with chronic granulocytic leukaemia (CGL) in transformation treated with cytotoxic drugs (Goldman *et al*, 1978a). The possibility that haematological recovery in that patient was spontaneous and unrelated to the autograft was not rigorously excluded. Subsequently we reported rapid haematological recovery following autografting in additional patients, two of whom had received cytotoxic drugs plus total body irradiation (TBI) to 600 rads (Goldman *et al*, 1979). More recently we have treated patients with 900 and 1000 rads TBI in preparation for autografting (Goldman, 1979). The speed of haematological reconstitution in these different patients was broadly comparable and more rapid than the reconstitution that follows grafting with normal allogeneic or syngeneic marrow cells (Thomas *et al*, 1977; Fefer *et al*, 1974). We have therefore concluded that

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The Newcastle upon Tyne Hospitals NHS Foundation Trust

Intrathecal Cytotoxic Chemotherapy (ITC) Policy

Version No.:	3.3
Effective From:	6 November 2015
Expiry Date:	3 June 2017
Date Ratified:	14 October 2015
Ratified By:	Medicines Management Committee

1 Introduction

Intrathecal chemotherapy administration refers to the administration of a cytotoxic drug into the cerebral spinal fluid either via a lumbar puncture or through an intraventricular route.

The administration of intrathecal drugs is potentially dangerous and must only be undertaken by staff that have undergone appropriate training and are certified as competent to participate in the process.

The administration of certain cytotoxic chemotherapy drugs, such as Vincristine, via the intrathecal route is almost always fatal (DoH 2008). Although the most recent National guidance relaxed some of the requirements compared to previous versions (DoH 2008) the Trust intrathecal chemotherapy group made the decision to keep these unchanged.

Vinca alkaloids: - Vincristine, Vinblastine & Vinorelbine and Vindesine are all fatal if administered intrathecally. They MUST only be given INTRAVENOUSLY. This must be compliant with the NPSA Rapid Response Report (NPSA/2008/RRR04) on vinca alkaloid administration. For further details see Appendix 6

This policy should be read in conjunction with other Trust policies, procedures and guidelines including those pertaining to consent, cytotoxic chemotherapy, administration of medicines and sedation.

The key recommendations outlined within this document are as follows:

- ITC can only be administered to adult and paediatric oncology patients at designated times and in designated areas within the Trust.
- Clinical staff who wish to be included on the Trust ITC Register must undertake appropriate training and demonstrate competence in their registered task prior to inclusion on the Trust ITC Register.
- Only competent and designated personnel, whose names are recorded on the Trust ITC Register, are authorised to prescribe, verify, dispense, issue, check or administer ITC.
- A competent Consultant, Specialist Registrar or Speciality Doctor, listed on the Trust ITC Register, using a designated ITC prescription chart, **MUST** prescribe

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