

Oklahoma Society of Clinical Oncology
POLICY AND POSITION STATEMENT
PREPARATION, STORAGE, DELIVERY AND ADMINISTRATION OF CANCER CARE
DRUGS

Introduction

The Oklahoma Society of Clinical Oncology (OSCO) is adopting this policy on the proper preparation, storage, delivery and administration of cancer care drugs in order to describe the best practices in oncology that provide cancer patients the optimal quality of care. Outpatient chemotherapy and antibody therapies are administered in physicians' offices, hospital outpatient departments and freestanding cancer centers to provide patients premium and beneficial cancer care. The safety of patients and health care employees is of the top priority.

The American Society of Clinical Oncology has addressed the safety concerns of oncologists in any arrangement whereby patients receive chemotherapy from an infusion center, home care agency, physician office or cancer center that are required to receive drugs prepared or obtained by another entity under contract with the third-party payer.

OSCO is issuing this statement to define the appropriate conditions for preparation, storage, delivery and administration of cancer drugs to meet all concerns for patient and employee safety. In order to achieve the essential safety checks and balances necessary to minimize errors in drug mixing and delivery, it is imperative that the least amount of steps be taken in preparing and administering cancer treatment drugs to the patient.

Background—Cancer Treatment Drug Preparation, Storage and Shipment

Safety standards for chemotherapy preparation, storage and shipment are set by agencies such as the National Committee for Quality Assurance, Americans with Disabilities Act, Occupation Safety and Health Administration and the Clinical Laboratory Improvements Act. The Centers for Medicare & Medicaid Services (CMS) require physician supervision for patient safety. The Food & Drug Administration has stated its concern about counterfeit drugs and advocates treatment centers maintain strict control of their drug supply and distribution chain. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires hospital-based outpatient centers to monitor and maintain records that ensure safe acquisition, control and distribution of all drug products.

Cancer treatment facilities have provided laminar flow hoods to facilitate a safe environment for mixing drugs at the point of service. Provisions for the safe storage and disposal of cytotoxic cancer treatment drugs are required. Gloves and other disposable protective clothing are essential for staff during the preparative process. Dose checking calculation systems, meticulous labeling and attention to patient identification are imperative to prevent drug administration errors.

Cancer research continues to introduce many new drugs to the oncology market. Some of the most successful agents are monoclonal antibodies that are utilized in conjunction with chemotherapy drugs. Monoclonal antibodies require specific storage (refrigeration), mixing and administration procedures that can be routinely complicated. Cancer treatment facilities must adhere to the new packaging requirements to prevent loss of drug efficacy.

Cancer drug therapies are administered in outpatient environments that ensure patient comfort and safety. Patients may also be pretreated with additional drugs to prevent nausea, hypersensitivity reactions including hypotension, anaphylaxis and fever. Monitoring of patients after cancer treatments is routine to ensure safe administration to inpatients and outpatients.

Documentation of proper orders, mixing, administration and patient tolerance is fundamental for competent cancer drug therapy. This complex process requires authorized physicians, certified nurses and other experienced professionals including oncology pharmacists. Provisions of all levels of emergency support must be available during chemotherapy or monoclonal antibody administration.

OSCO Policy and Position Statement

Page -2-

Guidelines for Preparation, Storage, Delivery & Administration of Cancer Treatment Drugs

(Source American Society of Clinical Oncology statement, updated December 2, 2003)

- 1) A physician who is trained and/or experienced in administering antineoplastic agents supervises administration of chemotherapy.
- 2) Professional staff specifically trained in chemotherapy management administers chemotherapy. Licensure or specific certification as an oncology nurse is eminently desirable.
- 3) Physicians and nursing staff have CPR training.
- 4) Medications for the treatment of anaphylaxis, including oxygen, are immediately accessible.
- 5) An appropriately trained physician is physically present when a drug or biologic is administered in the event anaphylaxis or other emergencies occur.
- 6) The facility has written guidelines to manage chemotherapy extravasation.
- 7) The facility has written guidelines to detect and prevent over- and underdosing of antineoplastic and supportive care drugs.
- 8) Chemotherapy and antibody drugs are prepared in an appropriate environment and manner to ensure sterility and stability. The safety of the personnel preparing the drug is essential by providing relevant equipment, protective clothing and disposal facilities.
- 9) The drug is prepared within the manufacturer's labeled expiration date.
- 10) Efforts to prepare drugs in the precise dilution and manner in which the manufacturer has recommended are imperative.
- 11) The drug is administered in a timely fashion following preparation in compliance with instructions written by the manufacturer and approved by the Food & Drug Administration.
- 12) The drug is available to follow the exact schedule prescribed by the treating physician to meet the needs of the patient.
- 13) Efforts are expended to ensure that individuals receive the drug and dose prescribed.
- 14) Proper storage of all medications, according to package guidelines, is crucial to assure stability.

Outside Services Providing, Preparing and/or Administering Cancer Care Drugs

The hematologist and oncologist assume the responsibility and liability for the patient's care when prescribing the use of cancer care drugs. Alternative means of supplying, preparing or administering cancer drug treatments, compromise the physician's responsibility for a patient's overall care.

It is unwise to substitute inept alternatives to a system that currently provides the highest quality of cancer care in outpatient facilities. OSCO is concerned that the quality of care and the safety of patients will be compromised by permitting outside services to provide, prepare and/or administer drugs to treat malignancies.

Therefore, the Oklahoma Society of Clinical Oncology has adopted the position to oppose any and all efforts by insurance companies, managed care organizations, and other payer entities to compromise long standing safety, chain of custody, and safe storage/handling procedures.

Further, OSCO views these efforts as an imposition of restrictions on our patient's access to safe and appropriate cancer care and as an act intended to diminish the Oncologists' role of comprehensive oversight and supervision of optimum patient care and cancer treatment.

The complex prerequisites of current cancer drug therapy outlined in the above guidelines have been adopted in facilities that strive to provide optimal care to patients. Patients depend on the physicians and their staff to provide these services with the ultimate quality. By focusing care at the point of service, competent patient safety, efficacy and support are ensured.

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