

Position Statement on safe handling of monoclonal antibody drugs

Introduction

The Cancer Nurses College New Zealand Nurses Organisation (NZNO) has recognised the need to develop a position statement to guide cancer nurses nationally in the safe handling of monoclonal antibody drugs (MAB's). The National Nursing Standards for Antineoplastic Drug Administration overarch this document.

Monoclonal antibody drugs have historically been considered a subcategory of antineoplastic drugs and due to a paucity of evidence, handled with the same precautions. Evidence now suggests this may not be necessary due to the structure of these drugs. A number of international organisations have developed guidelines on safe handling and administration of monoclonal antibodies. They form the basis of this position statement and are included in the reference list. ^{1 2 3 4 5}

Risk Factors

The risk factors considered for monoclonal antibody drug exposure include internal exposure via dermal, inhalation, and mucosal absorption.² All currently available MABs have a low risk of internalisation at occupational exposure levels.³

Internal exposure may pose a potential risk of:

- Toxicity
- Cytotoxicity
- Carcinogenicity
- Geno toxicity or mutagenicity
- Teratogenicity or developmental toxicities
- Organ toxicity at low doses
- Immunogenicity

Position/Recommendations

It is the current position of the Cancer Nurses College NZNO that cancer nurses involved in the handling and administration of monoclonal antibody drugs should:

- Not be involved in the preparation of these drugs.
 Preparation requires specific techniques and/or conditions and should be undertaken in a clean pharmacy room by appropriately trained pharmacy staff using appropriate personal protective equipment (PPE).⁵
- Nurses involved in administration should wear gloves as a minimum standard PPE. ¹²³ Current MABs have a high molecular weight therefore dermal absorption across intact skin, is unlikely. Gloves and effective hand hygiene are recommended to reduce risk.²



• The use of an apron, mask and protective eyewear remain optional PPE for situations in which the nurse involved deems there is personal risk of exposure.

Consider use: during administration of IV preparations where the dis/connecting administration lines may present a risk of aerosolisation, particularly with new or inexperienced staff. 1

- In handling of MAB's which are conjugated with a cytotoxic or radiopharmaceutical, full cytotoxic or radiopharmaceutical PPE should be worn as per local area policy.³
- Biosimilar drugs should be handled in the same manner as the original MAB drug.
- Waste products should be handled using standard precautions³ unless handling a MAB in conjugated form. In this instance, local area policy for cytotoxic or radiopharmaceutical waste management should be followed.

Other evidence

Australian and UK guidelines suggest there is no need for the use of Closed System Transfer Device (CSTD's) owing to the biological structure of these medications. There is however, evidence to suggest using CSTD's can reduce operator exposure. Although MAB's are not considered as hazardous as conventional chemotherapy, nurses can be subjected to low level exposure over time.

Planning pregnancy, pregnancy or lactation – evidence is entirely lacking about risk, we recommend reviewing the NIOSH hazardous drugs list for risk category of drug/s being exposed to and discussing safety with your employer.

For future MABs with different physiochemical properties, smaller molecule size, formulations demonstrating to alter absorption and lower permeability, appropriate handling should be reassessed.

References

- 1. <u>Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel. WCMICS. 2014.</u>
- 2. <u>Clinical Oncology Society of Australia (COSA) Position statement: Safe handling of monoclonal antibodies in healthcare settings, 2013.</u>
- 3. eviQ safe handling of monoclonal antibodies
- 4. eviQ hazardous drugs table
- 5. Centre for Disease Control and Prevention NIOSH hazardous drugs list