Position statement on the safe handling of monoclonal antibody drugs

2025 update

Cancer Nurses College - New Zealand Nurses Organisation

Contents

Introduction

Monoclonal antibodies (mABs) are an increasingly prevalent therapeutic option available in the management of malignant conditions in New Zealand and offer significant benefits for the patient.

mABs have historically been considered a subcategory of antineoplastic drugs and, due to the 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 the safe handling and administration of monoclonal antibodies. They form the basis of this position statement and are included in the reference list.

Risk Factors

There is limited research regarding the consequences of longer term, low dose occupational exposure for those preparing and administering mABs and as such consideration should be given to risk factors for exposure.

The risk factors considered for monoclonal antibody drug exposure include internal exposure via dermal, inhalation, and mucosal absorption.

mAB exposure may pose a potential risk of:

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

We note that due to mAB large molecular size and weight, literature suggests that all current available mABs have a low risk of internalisation at occupational exposure levels - **however there is limited research on the long-term impact of occupational exposure.**

Practice Point:

It is important to differentiate the risks and recommendations for mABs, and that of mAB conjugates.

mABs themselves are not cytotoxic and the recommended handling precautions reflect this.

mAB Conjugates are cytotoxic as such, cytotoxic precautions should be followed for handling. Due to the cytotoxic risks posed by Mab conjugates, these must always be compounded in a centralised aseptic production unit.

Position Statement

Cancer Nurses College position and recommendations:

It is the current position of the Cancer Nurses College NZNO, that cancer nurses should not be involved in the preparation of monoclonal antibodies (mABs) **unless** a short expiry date would make it prohibitive for this to be provided to the point of administration in a compounded form - particularly in the context of remote/rural administration settings.

It is the expectation of the Cancer Nurses College that any mAB which demonstrates an expiry time in which it would be feasible for this to be provided in the compounded format, be provided compounded as a standard operating procedure.

Additionally, it is the expectation that any nurse involved in the compounding of mABs be provided with the appropriate training in asepsis and compounding techniques prior to undertaking this task independently. Any organisation which requires nurses to complete compounding need to have a documented training and competency assessment pathway, and relevant policy and procedures available to support this.

Compounding

If a cancer nurse is required to participate in the compounding of monoclonal antibodies to facilitate care, the following should be adhered to:

- The compounding of mABs is to be completed in a dedicated clean space, away from the bedside.
- With nursing ratios that support nursing time to complete all manipulations distraction free and uninterrupted.
- All compounding should utilise a closed system transfer device.
- Vial sharing should not be utilised.
- The mAB should only be prepared immediately prior to administration once a satisfactory patient assessment has been completed.
- There should be a second mAB compentent nurse avaliable to second check compounding procedures, as well as the 5+7 rights in accordance with organisational procedures.
- The nurse should be familar with the mAB that they are compounding and be able to demonstrate an understanding of the specific properties of this mAB.
- Risk assessment is completed for the specific drug, by service provider and approved for the process of nurse compounding in remote site (see risk assessment section for further detail).

Recommended PPE to wear during compounding

- **Gloves (disposable, nitrile, over wrist cuffs - cytotoxic standard).**
- **Mask P2 (N95)**
- **Protective eye wear**

Pregnant or currently immunocompromised staff should not be involved in the preparation of monoclonal antibodies

Risk Assessment

There are several patient safety risks that have been identified associated with the preparation of mABs in settings other than a centralised aseptic production unit. These include:

- Incorrect preparation technique (i.e., flocculation)
- Unintended volume loss and incorrect dosing
- Increased infection risk related to decreased level of asepsis
- Medication errors

The complexity of mAB preparation increases risk of error.

Complex preparation techniques and numerous manipulations are more prone to error and should not be completed outside of a centralised aseptic production unit.

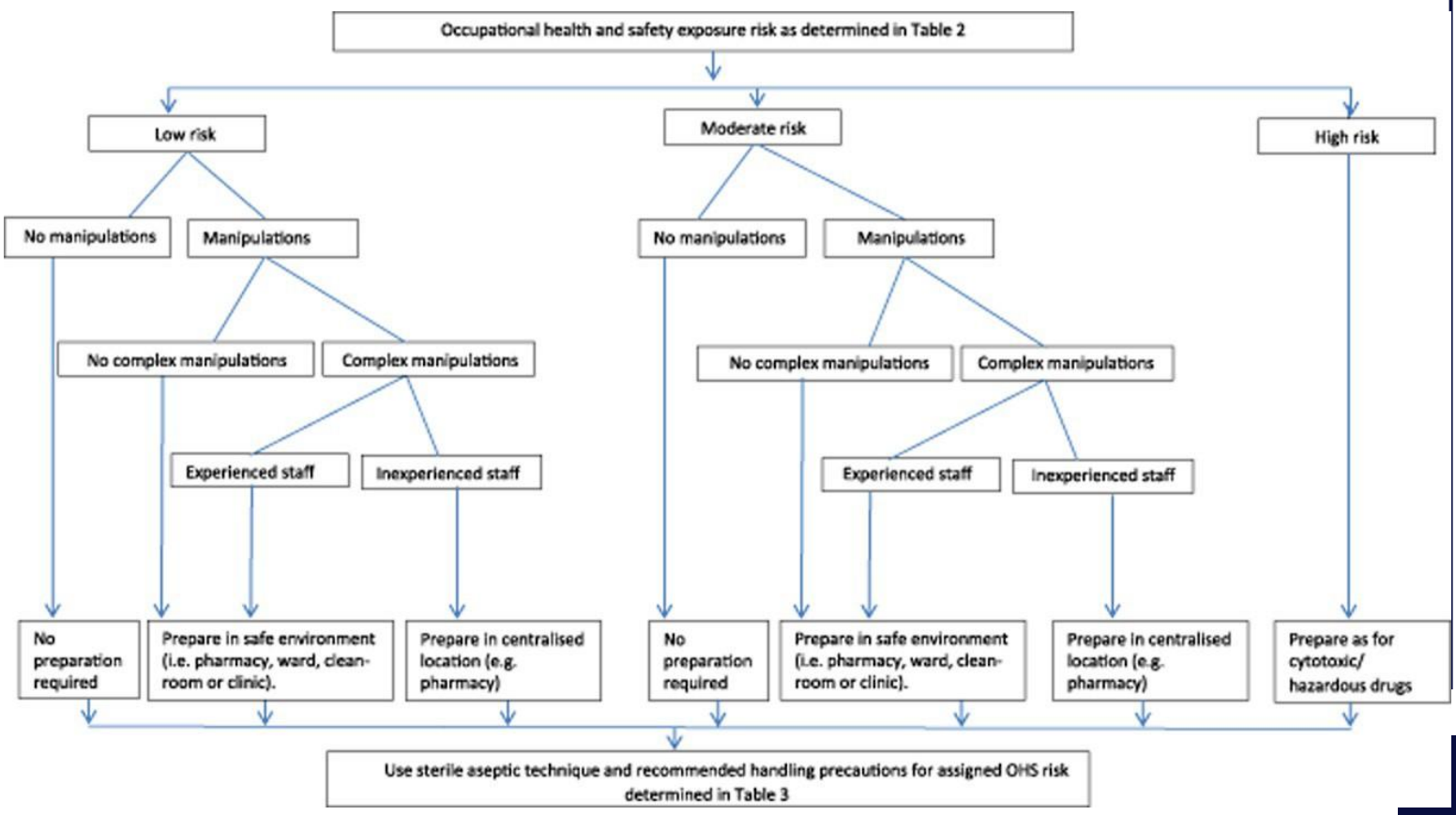
Additionally, risk of error further increases when performed by inexperienced staff. Staff experience and training are crucial determinants to ensuring safe and high-quality preparation.

It is critical that a risk assessment is completed by the service provider regarding the complexity of compounding to assess the suitability of the proposed mAB to be compounded in a remote/rural site.

Practice Point - Recommended risk assessment

The Cancer Nurses College recommends utilising a risk matrix outlined in the the Australian Consensus Guidelines for the safe handling of mAB for cancer treatment by healthcare personal (figure 1).

Risk assessment matrix



Note: Occupational health and safety exposure risk. From Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel by Alexander et al., 2014, J*Internal Medicine Journal, 44(10), 1018-1026*

The Cancer Nurses College recognise that the ability for nurses to complete the compounding of short-expiry mABs as critical for equitable service provision and the ability for patients to receive cancer care closer to home.

The only mABs recommended for preparation at a remote/rural site are those that are deemed safe in accordance with the above risk matrix.

Administration of mAB

The Cancer Nurses College recognise that mABs do not demonstrate the same risk profile of cytotoxic drugs due their large molecular structure and therefore do not require the same level of PPE during administration.

- Nurses involved in administration should wear **gloves** as a minimum standard of PPE.

Current mABs have a high molecular weight therefore dermal absorption across intact skin, is unlikely. Gloves and effective hand hygine are recommended to reduce risk.

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

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

- The use of **closed administration sets is recommended** for the administration of mABs.

Safe handling of bodily fluids

Bodily fluids should be handled using standard precautions - unless the individual has been exposed to a mAB in a conjugated form. In this instance cytotoxic precautions should be utilised in accordance with your local area policy.

Spill management

Spillage of mAB medication should be managed in the same manner as a **cytotoxic spill**.

All staff involved in the preparation or administration of monoclonal antibodies should be familiar with their local cytotoxic spill policy and procedures, have a spill kit readily available, and be familiar with the spill kit contents and how to utilise these.

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