Hospital pharmacy practice update: Preparation of Mycobacterium bovis (Bacillus Calmette-Guerin) immunotherapy

HOSPITAL PHARMACY PRACTICE UPDATE

SHPA Compounding Services Leadership Committee

Situation

Mycobacterium bovis (Bacillus Calmette-Guerin (BCG) strain) is a preparation that may be used as part of the treatment of bladder cancer. Currently, preparation of BCG immunotherapy in Australian healthcare facilities is undertaken in either a dedicated biohazard cabinet, a non-sterile bench space or bedside on the ward.

Due to the potential risk of transmission and infection during preparation, it is recommended that BCG immunotherapy should be prepared in a dedicated biohazard cabinet.

Many hospitals that do not have a dedicated biohazard cabinet and are unable to outsource due to access and delivery issues, may not be able to install one, especially if demand for BCG immunotherapy is low.

Background

BCG is a live strain of attenuated Mycobacterium bovis, which produces a local inflammatory reaction, resulting in elimination or reduction of superficial tumour lesions of the bladder.[1–4]

Due to the potential risk for transmission and infection of personnel, the manufacturer states that it should be prepared, handled and disposed of as a biohazard material.[1] The New South Wales (NSW) Cancer Institute states that BCG infections have been reported in healthcare workers, primarily from exposure resulting from accidental needle stick injury or skin lacerations during the preparation of BCG for administration.[5] The manufacturer also advises that there is a risk of accidental exposure through self-inoculation, dermal exposure through an open wound, inhalation or ingestion.[1]

There are also risks associated with the cross contamination of other products with BCG. Nosocomial infections have been reported in immunosuppressed patients receiving parenteral drugs that were prepared in areas, in which BCG was also prepared.[5,6]

Once reconstituted, BCG is highly unstable, with a short expiry of four hours.[1,7]

Assessment

The United States Pharmacopeia (USP) states that BCG should be prepared in a Containment Primary Engineering Control (C-PEC) located in a Containment Secondary Engineering Control (C-SEC).[8]

The Society of Hospital Pharmacists of Australia (SHPA) guidelines and Australian Injectable Drugs Handbook (AIDH) states that materials containing live vectors must be handled in a dedicated facility for biohazardous material (and not in the same cabinet where cytotoxic drugs are prepared).[7,9]

The NSW Cancer Institute states that wherever possible, BCG should be prepared by a pharmacist using a biocontainment hood. [5] If a biocontainment hood is not available the pharmacist or individual responsible for preparing the agent should wear gloves, mask and gown and face shield, and use a closed system containment device for the reconstitution of the BCG, to avoid inadvertent exposure to broken skin or inhalation of BCG. To avoid cross-contamination, parenteral drugs should not be prepared in areas where BCG has been in use.

A number of studies on cytotoxic compounding have found that the use of a closed-system transfer device (CSTD) in conjunction with a pharmaceutical isolator can significantly reduce contamination of the workstation and the external surfaces of prepared bags and syringes, eliminate potential needle stick injuries, and reduce risk of exposure to staff.[10–14] It is important to note that while contamination is reduced by using a CSTD, it is not completely eliminated.

The British Association of Urological Surgeons states that[15]:

- Best practice preparation of BCG immunotherapy in a pharmacy department is carried out in a dedicated biohazard cabinet to minimise the risk to the operator and risk of cross contamination
- Operators involved in preparation should have their immunity to tuberculosis checked using the Heaf Test

Systems and practice recommendations

SHPA recommends that health services adopt a risk management approach to the compounding of BCG immunotherapy that is adherent to the *Preventing and Controlling Healthcare-Associated Infection Standard*[16] in the National Safety and Quality Health Service Standards and workplace health and safety regulations.

Thus, due to the potential risk of transmission and infection during preparation, SHPA recommends that BCG immunotherapy should be prepared in a dedicated biohazard cabinet by appropriately trained compounding pharmacists and pharmacy technicians.

VERSION	**1**
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