



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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Safe Compounding; it's in your Hands

INTRODUCTION

Cytotoxic chemotherapy is one of the most frequently used treatments for cancer. Unfortunately, it is well known that preparing cytotoxic agents is potentially hazardous for the operator. Cytotoxics are known to be:

- Mutagenic
- Carcinogenic
- Teratogenic¹.

The gloves currently in use in the Regional Oncology Haematology Pharmacy (ROHP) are:

- **Ansell Sensiclean**[®] latex gloves for receiving drugs, preparing trays, spraying items into the isolator, removing items from the isolator and for the final check of products.
- **Bioclean Emerald**[®] gloves as an underglove for compounding and for all activities for operators who have an allergy to latex.
- **Berner Z Plus**[®] gloves as an overglove for compounding.
- **Chemoprotect**[®] gloves for washing trays which were used during compounding of cytotoxics.

AIM

To determine whether the gloves in current use at the (ROHP) are the most appropriate type for handling and compounding cytotoxic drugs.

METHODS

- 1) Literature review of best practice recommendations was performed.
- 2) Surveyed other hospitals and commercial compounding units about the types of gloves used when handling cytotoxics.
- 3) Contacted glove manufacturers to find out what they recommend for handling and compounding cytotoxics and attained samples on foot of these recommendations.
- 4) Assessed different gloves in terms of permeability to cytotoxics, comfort, cost and sterility.

RESULTS

1. Literature Review

There have been a number of studies conducted comparing permeabilities of different types of gloves to different cytotoxic agents. It is difficult to compare the results of these studies as they were undertaken using different glove types and thicknesses, different experimental conditions and using different types of cytotoxic drugs.

Best practice recommendations on choosing a glove type²:

- 1) Select powder-free gloves.
- 2) Longer gloves that cover gown cuff protect wrist from exposure.
- 3) Double-gloving is better than one thicker single glove.
- 4) Change gloves every hour or immediately if contamination occurs.
- 5) Inspect gloves for visible defects before use.
- 6) Use good quality gloves that have been tested for permeability to hazardous drugs.

Three main glove types are used for handling cytotoxics.

Glove Type	Advantage	Disadvantage
Latex	Recommended by OSHA ³ for handling cytotoxics. Good elasticity. Affordable.	Operators allergic to latex cannot use. Resistance to puncture and permeability depends on thickness of the glove being used.
Neoprene	Allergy is not a problem. Very comfortable.	More expensive than latex. Less puncture resistant than others.
Nitrile	Very high tensile strength. Excellent barrier to harsh chemicals. Highest puncture resistance.	More expensive than latex.

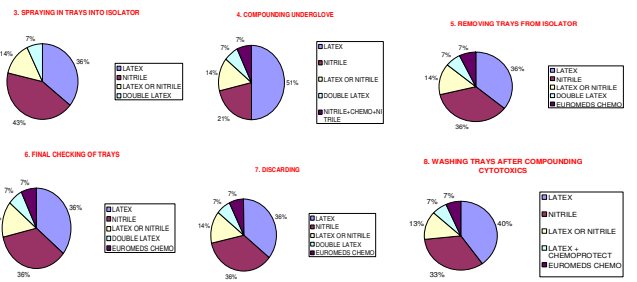
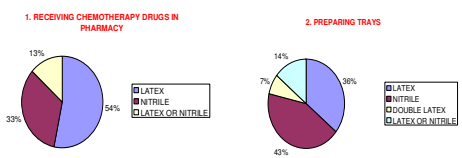
Studies by Wallemacq et al have shown latex gloves with a thickness of at least 0.24mm and nitrile gloves with a thickness of at least 0.16mm have high resistance to permeation to cytotoxics⁴.

Standards

Currently there are two standards for testing permeability of gloves to cytotoxics; a **European** (EN 374-3; 2003) and an **American** (ASTM D 6978-05) standard. The American standard is much more robust. When comparing glove types they should perform well in the American test.

2. Hospital and Commercial Compounding Unit Survey

The survey showed a wide variation in the types of gloves used in different centres and for different activities. This highlights the absence of an agreed standard in Ireland for handling cytotoxics.



3. Glove Manufacturers' Recommendations

Based on the survey, three main glove manufacturers were identified.

- 1) Nitritex
- 2) Ansell
- 3) Berner

The samples received were assessed and rated for comfort in the pharmacy. Technical information on each glove type (including information on permeability to cytotoxics) was collated and prices obtained.

It is difficult to compare the protection provided by the different gloves available. Glove manufacturers use different permeation tests. Some gloves are only available in sterile form. Gloves with permeation data are more expensive as are sterile gloves. All gloves which comply with the American Standard are sterile and expensive.

Practice in the ROHP was modified to incorporate the results of this study (See conclusion).

CONCLUSIONS

Ideally, permeation data should be assessed for each glove type and for each individual cytotoxic drug.

The type of glove chosen in a compounding unit will depend on the risk of exposure for each activity and the type of cytotoxic drugs handled in the unit.

Based on this study, we have changed the type of gloves used for some activities in the pharmacy. Sterile gloves were chosen for activities in the isolator room. Gloves which comply with the American standard were chosen for activities with a higher risk of exposure. Less expensive non-sterile gloves were chosen for lower risk activities.

The following gloves were found by staff to be the best for the tasks outlined:

Glove type	Use in ROHP	Features/physical properties	Comply with US Standard for permeation to cytotoxics?	Comments
Bioclean Ultimate [®]	Spraying into isolator, removing trays from isolator, final check of products.	Latex free. Co-polymer blend	Yes. Permeation time of >480 mins for all drugs used in ROHP	Sterile Expensive
Bioclean Emerald [®]	Underglove for compounding	Latex free. Nitrile	Yes. Permeation time of >480 mins for all drugs used in ROHP	Sterile Expensive
Berner Z Plus [®]	Compounding	Latex	No. Tested to European standard. Permeability times of 180 mins for all drugs used in ROHP. Recommend change gloves every 30 mins*.	Sterile
Omega [®] Nitrile	Tray set up. Receiving cytotoxics in the pharmacy	Latex free. Nitrile	No. But glove has thickness of at least 0.16mm and so permeation unlikely	Non sterile Low cost
Braun Vasco Sensitive [®]	Tray set up. Receiving cytotoxics in pharmacy	Latex	No. Recommend double glove. Each glove has ~0.24mm thickness and so permeation unlikely.	Non sterile Low cost
Chemo-protect [®] gloves	Washing trays used during compounding	Latex	No. These should be worn over other gloves. Comply with European Standard	Non sterile.

* Staff chose this glove for compounding, even though the manufacturer recommends changing every 30 mins. This glove was easiest to change in the isolator and comfortable to use. The underglove has permeation data up to 480mins for all drugs used in the ROHP, so staff will be protected in the event of accidental spillage. (Accidental spillage on Berner Z plus gloves would not be expected to affect the integrity of the isolator).

References

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