

COMPARATIVE STUDY OF THE DIFFERENT CLOSED SYSTEM TRANSFER DEVICES AVAILABLE IN FRANCE FOR THE PREPARATION OF INJECTABLE IMMUNOTHERAPIES.

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INTRODUCTION

The Centralized Cytotoxic Reconstitution Unit (CCRU) currently uses Closed System Transfer Devices (CSTDs) in downgrade mode for the preparation of immunotherapies. Losses of products have been observed to a greater or lesser extent depending on the molecules. Monoclonal antibodies being expensive molecules, product loss has a real economic impact.

Comparison of the CSTDs available in France to allow a given institution to choose the most suitable device for their needs.

MATERIALS AND METHODS

Training in the use of each CSTD by interns and pharmacy technicians

Measurement of product loss with a dummy product: lidocaine

Statistical study on the volume of product loss: ANOVA test (analysis of variances)

Evaluation of devices and creation of a scoring grid

Use of CSTDs in the CCRU: preparation of monoclonal antibodies

Evaluation of the tightness by a visual test with fluorescein

Practicality

Safety

Comfort

Handling time

Cost

RESULTS

Main characteristics of the different CSTDs

Tevadaptor® (Carelide)

- one reference for all sizes of bottles
- easy to use and ergonomic
- possibility to disconnect the syringe

Equashield® (Equashield)

- time saving and safety: connected syringe + secure connection with indicator
- many references
- ergonomics: poor grip

ChemoClave® (ICU Médical)

- simplicity and rapidity of use
- difficulty to collect the entire amount of the vial
- easily disconnected

PhaSeal Optima® (BD)

- Optimization of the previous system (PhaSeal®)
- ambient air sampling
- resistance to sampling
- many steps

PhaSeal® (BD)

- easy sampling
- many references
- many steps
- connection not secure and not very practical

QimoHarpoon® (Vygon)

- sterile air balloon
- few references
- no disconnection possible
- many steps
- practicality: many elements, complicated grip

$$\frac{\sum x^2 - \frac{(\sum t_i)^2}{n}}{N-c}$$

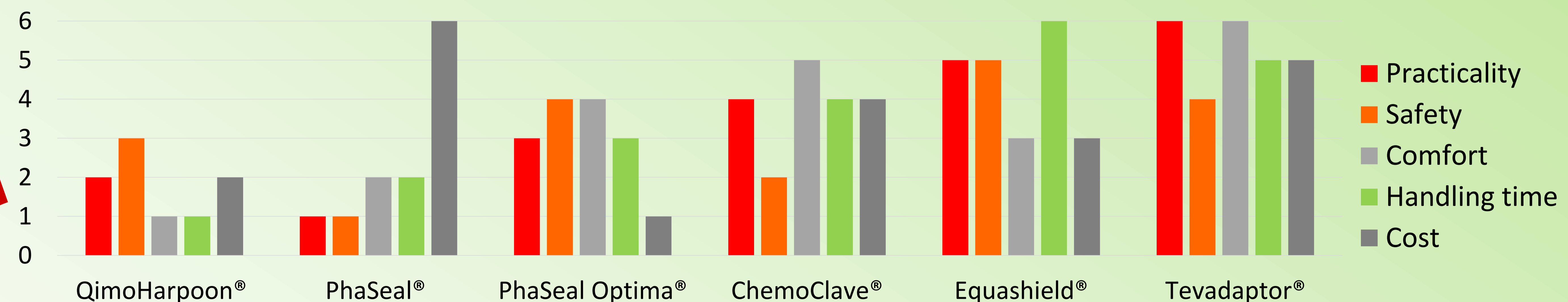
Results of product loss measurements

| Device name | Average volume of loss in mL |
|-----------------|------------------------------|
| PhaSeal® | 0,4371 |
| PhaSeal Optima® | 0,2115 |
| QimoHarpoon® | 0,3341 |
| ChemoClave® | 0,4318 |
| Tevadaptor® | 0,3287 |
| Equashield® | 0,2818 |

Statistical study : ANOVA test - analysis of variances.

There is **no significant difference** in terms of product loss between the different CSTDs.

Results of the scoring grid



Tevadaptor® > Equashield® > ChemoClave® > PhaSeal Optima® > PhaSeal® > QimoHarpoon®

CONCLUSION

The degree of requirement of the manipulations carried out corresponds to the expectations of chemotherapy units. The loss of product and the tightness are not the main criteria for choosing a CSTD. Moreover, a high price is not linked to a better use in practice. As a result, this study presents the strengths and weaknesses of each CSTD and could be a good decision support tool to help a given institution to choose a CSTD, according to its criteria.