Economic impact of extending the beyond-use date of chemotherapy single-dose vials through the use of a closed-system transfer device

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Background

- The United States Pharmacopeia Chapter <797> standards state that single-dose vials (SDV) must be discarded 6 hours after the first vial access if accessed and kept in ISO class 5 air conditions, otherwise the vial should be discarded after 1 hour[1]
- The purpose of this standard is to decrease the potential for bacterial contamination of medications, but this mandate leads to the waste of high-cost, chemically stable drugs
- The Equashield® closed-system transfer device (CSTD) was shown to prevent microbial contamination of preservative-free SDV for 9 days after being accessed 10 times over a 7 day period,[2] and consequently, the FDA approved extending the beyond-use date (BUD) of SDV to 7 days through the use of the Equashield® CSTD in May 2014[3]
- The Mount Sinai Hospital (MSH) has been using the Equashield® CSTD for the preparation and administration of hazardous drugs since 2011, and recently implemented BUD of chemo/biotherapy SDV in concordance with the recent FDA approval
- Our one month cost analysis study in 2013 estimated a potential cost savings of more than $20,000 per month by extending the BUD of SDV chemo/biotherapy to 7 days at our institution

Objectives

- To assess the cost savings of extending the BUD of SDV of chemo/biotherapeutic agents through the use of the Equashield® CTSD
- Primary objectives
  - To assess actual chemo/biotherapy wastage: cost of chemo/biotherapy discarded after implementing BUD of SDV
  - To assess potential chemo/biotherapy wastage: cost of chemo/biotherapy that would have been discarded if BUD of SDV was not implemented
- Secondary objectives
  - Total number parenteral chemo/biotherapy preparations compounded
  - Estimated cost of Equashield® products used
  - The combined cost of wasted chemo/biotherapy and Equashield® products

Methods

- A prospective economic analysis of all discarded liquid SDV of chemo/biotherapeutic agents from October 1st to October 30th 2014 (30-day study period) was performed at the MSH
- Wasted amount of the 28 eligible chemo/biotherapeutic agents for the study (table 1) were documented on a daily basis
- The potential wastage of medications that would have been discarded if the vials were not reused for 7 days was also recorded
- 340B price was used for ambulatory use and non-340B price was used for inpatient use for this cost savings analysis

Results

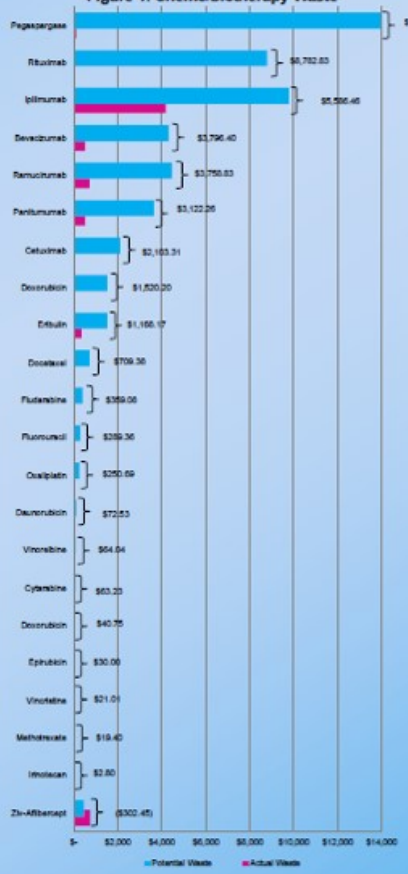
Table 1. Chemo/biologic agents included in the cost savings analysis (n=28)

Bevacizumab	Epirubicin	Oxaliplatin
Busulfan	Eribulin	Panitumumab
Cetuximab	Fludarabine	Pegaspargase
Cladribine	Fluorouracil	Pertuzumab
Clofarabine	Idarubicin	Ramucirumab
Cytarabine	Ipilimumab	Rituximab
Daunorubicin	Irinotecan	Vincristine
Doxorubicin	Methotrexate	Vinorelbine
Doxorubicin Liposomal	Nelarabine	Ziv-aflibercept
	Ofatumumab	

Table 2. Preparation and wastage data for chemo/biotherapy during 30-day study period

Total number of parenteral chemo/biotherapy preparations made	4207
Number of parenteral chemo/biotherapy preparations included in this analysis (see table 1)	806/4207 (19%)
Total cost of wasted chemo/biotherapy (actual/potential)	$7,248 (Actual) vs. $51,441 (Potential) = $44,192 cost savings with BUD
Total estimated cost of Equashield® devices used	$19,686
Total cost of chemo/biotherapy wasted plus Equashield® (actual/potential)	$26,934 (Actual) vs. $71,026 (Potential) = $44,192 cost savings with BUD

Figure 1. Chemo/biotherapy Waste



Discussion

- Top six medications that represented the most cost savings were pegaspargase, rituximab, ipilimumab, bevacizumab, ramucirumab, and panitumumab
- Implementation of BUD of chemo/biotherapy SDV using Equashield® CSTD allowed for a significant cost savings of $44,192 during the one month study period, translating to an estimated cost savings of approximately $530,000 annually
- While implementing Equashield® CSTD represented an increase in annual expenditures of about $235,000, the resulting net cost savings by implementing BUD using this device ($530,000/year) not only offset the cost of CTSD, but also resulted in a significant cost savings to our institution

Recommendation

- Cost analysis using a longer study period (3-6 months) will represent more accurate estimated annual cost savings

Limitations

- Due to the short study period (30 days), chemo/biotherapeutic agents used during this study period may not represent those used throughout the year
- BUD of chemo/biotherapy was implemented before the study period, therefore, our study included partially used vials that were initially opened before the study period, leading to potential underestimation of our cost savings

References

1. Pharmaceutical compounding—sterile preparations (general information chapter 797). In: The United States Pharmacopeia, 34th rev., and The National Formulary, 29th ed. Rockville, MD: United States Pharmacopeial Convention; 2011, pp.336–373.
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Disclosures

- Authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation