COSTS AND REIMBURSEMENTS FOR BACTERIAL RISK CONTROL STRATEGIES FOR PLATELETS: RESULTS FROM A HOSPITAL BUDGET IMPACT MODEL

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INTRODUCTION

- Evolving FDA guidance pertaining to bacterial risk control strategies (BRCS) for platelets presents challenges in understanding the costs of these options.
- In addition to conventional primary bacterial testing and previously approved rapid secondary bacterial testing and pathogen reduction technologies, the December 2018 and September 2019 FDA guidances have introduced large volume delayed sampling with either a 36- or 48-hour hold, and secondary culture-based approaches, either an 8mL aerobic-only sample, or 16mL anaerobic and aerobic sampling.
- Our prior work yielded an interactive Excel-based model assessing the budget impact and shelf life implications of adopting pathogen reduction technology from the US hospital transfusion service perspective.
- As the BRCS landscape evolves, this model must be updated to remain relevant to these decision makers.

OBJECTIVE

- The objective of this project was to update our prior model to include the newly introduced BRCS and to compare costs, reimbursements, and shelf life impact of three BRCS from the perspective of a mid-sized US hospital transfusion service.

METHODS

- A previously published Excel-based hospital platelet budget impact model was updated to include all new BRCS per the December 2018 and September 2019 FDA guidances.[1-3]
- Four scenarios were generated to compare annual costs of acquisition, wastage, dispensing/transfusion, and septic adverse events for a hospital that purchases 100% of its platelet components (PCs):
  1. 100% conventional (C-PC)
  2. 100% large volume delayed sample (LVDS) ≥36h
  3. 100% pathogen-reduced (PR)
  4. A mix of 75% PR/25% LVDS
- Model assumptions were informed by published literature and a prior national survey of hospital transfusion services.[1]
- Costs are presented in $US 2019.

MODEL ASSUMPTIONS

- 3,016 5-day apheresis PC purchased annually
- 60.7% of non-PR PC are irradiated by the supplier
- Supplier's add-on NAT testing cost for emerging diseases is $7.50/unit
  - Add-on NAT testing cost is based on Zika testing, but can vary by institution and is modifiable in the model
- PR replaces irradiation, CMV testing, secondary bacterial detection strategies, and emerging disease testing[3-5]
- Secondary bacterial testing is not considered
- 26.3% of PC are outpatient transfusions (reimbursable) with half of transfusions billed to private insurance and half to CMS, 200% markup above unit cost for private insurance, and 75% payment for private insurance charges[6]
- Unit costs
  - *C-PC*: $557.70 non-irradiated; $607.70 irradiated
  - *LVDS*: $585.59 non-irradiated; $638.05 irradiated
  - *PR*: $665.20
- Mean age at time of receipt from supplier is 3 days for C-PC and LVDS and 2.37 days for PR
- Sepsis costs $80,000/case with probabilities of 1:10,288 for non-PR and 0 for PR[7-9]

RESULTS

- Total annual hospital costs, inclusive of acquisition, wastage, dispensing, transfusion, and septic adverse events, were $2,108,093 for the 100% C-PC scenario, $2,205,852 for the 100% LVDS scenario, $2,258,315 for the 100% PR scenario, and $2,245,200 for the 75% PR / 25% LVDS mixture scenario (**Table 1**).
- The maximum usable shelf life in both the 100% C-PC and 100% LVDS scenarios was 2 days (48.0 hours), as compared to 2.63 days (63.2 hours) in the 100% PR scenario and 2.48 days (59.4 hours) for the 75% PR / 25% LVDS mixture scenario (**Table 2**).

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RESULTS (continued)

Table 1. Annual Costs, Outpatient Reimbursements, and Net Costs

	100% C-PC	100% LVDS	100% PR	75% PR/ 25% LVDS
ANNUAL COSTS				
Acquisition	$1,795,643	$1,884,237	$2,006,243	$1,975,742
Wastage (expiration)	$126,200	$132,460	$90,043	$100,647
Wastage (mishandling)	$58,573	$61,478	$55,221	$56,786
Dispensing and transfusion	$106,808	$106,808	$106,808	$106,808
Sepsis	$20,869	$20,869	$0	$5,217
Total hospital cost	**$2,108,093**	**$2,205,852**	**$2,258,315**	**$2,245,200**
ANNUAL OUTPATIENT REIMBURSEMENTS	**$671,858**	**$695,183**	**$744,158**	**$731,915**
NET COSTS	**$1,436,235**	**$1,510,669**	**$1,514,157**	**$1,513,285**

Table 2. Shelf Life Impact

	100% C-PC	100% LVDS	100% PR	75% PR/ 25% LVDS
SHELF LIFE IMPACT				
Mean age at acquisition (days)	3.00	3.00	2.37	2.53
Maximum usable platelet life (days)	2.00	2.00	2.63	2.48

LIMITATIONS

- Our model does not include a recently announced LVDS pricing increase by a major blood supplier.
  - This increased price was announced 1 month before the meeting date and is $58 greater than our model's assumption.
  - We have not included it due to lack of published literature to support changing the assumption.
  - Updating the model to include this price increase would increase the magnitude of the net cost gap between C-PC and LVDS (C-PC would remain less expensive than LVDS) and also between PR and LVDS (LVDS would become more expensive than PR).
- Of the newly-approved BRCS, only 100% LVDS with a ≥36-hour hold was included in this comparative analysis.
- Rapid secondary bacterial testing was not included in this model.

CONCLUSION

- The 100% PR scenario was the most costly, but also experienced the largest reimbursements and yielded the largest maximum usable shelf life.
- After offsetting annual costs by reimbursements, the model predicts modest cost increases of 5.4% for PR versus C-PC, 0.2% for PR versus LVDS, and 0.2% for the mixed scenario with 75% PR/25% LVDS versus 100% LVDS.
- The 100% PR scenario represents an increase in usable shelf life of 31.7% versus 100% C-PC and 100% LVDS, and 6.4% versus the mixed scenario.
- Economic models are important tools for hospitals when considering the adoption of novel technologies.

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