COST AND SHELF LIFE IMPLICATIONS OF PATHOGEN-REDUCED PLATELETS:
A HOSPITAL BUDGET IMPACT MODEL

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INTRODUCTION

• In 2011, it was estimated that about 2.2 million units of platelets were transfused in the US.¹
• An FDA draft guidance has highlighted the need to reduce the risk of bacterial contamination of platelet components (PC) via pathogen reduction (PR) or rapid secondary bacterial testing (RT).
• Due to the expense of platelet components and transfusion, the variety of PC that are available, and emerging technologies, models that capture platelet-associated costs are needed to understand the hospital budget impact of PC choice and usage.

OBJECTIVE

• The objective of this project was to create an interactive Excel-based model to analyze the budget impact and shelf life implications of using different PC types from the US hospital transfusion service perspective.

METHODS

MODEL DEVELOPMENT

• Process maps capturing aspects of platelet management from acquisition through transfusion and adverse events were drafted.
  o Aspects considered include:
    • Acquisition (purchase and/or self-collection)
    • Storage
    • Secondary bacterial testing (Platelet PGD Test) or pathogen reduction (INTERCEPT Blood System)
    • Wastage
    • Dispensing for transfusion
    • Transfusion
    • Adverse events associated with (bacteremia, sepsis events)
• A survey was fielded to 27 US hospital transfusion service directors to understand their platelet management processes and usage patterns.
• Two site visits were performed to observe processes from the perspectives of both a hospital that purchases 100% of its PC and one that self-collects 100% of its PC.
• An Excel model framework was created following refinement of these process maps based on survey and site visits.
  o Model framework was populated with base-case costs and probabilities identified through both literature search and survey results.
• Model was refined after review by a panel of seven transfusion medicine physicians.
• An adaptive user interface was programmed on top of the model framework.
  o The user interface allows the pre-populated base-case assumptions to be overwritten with values specific to the end-user’s institution.

SCENARIOS CONSIDERED

• Three scenarios were evaluated in the model to compare annual costs of platelet acquisition, testing, wastage, dispensing, transfusion, adverse events, shelf life, and reimbursement for a hospital that purchases all of its PC:
  100% conventional (C-PC), 100% pathogen-reduced (PR-PC), and mix of 75% C-PC / 25% PR-PC.
• Model assumptions for the three scenarios:
  o Blood supplier (blood center) performs pathogen reduction, hospital performs secondary bacterial testing
  o 8,164 apheresis platelet units purchased annually with a 5-day shelf-life
  o 60.7% of C-PC is irradiated
  o 6.4% of C-PC are both CMV serology tested and irradiated at the hospital
  o PR replaces irradiation, CMV testing, Zika virus nucleic acid testing, and primary and secondary bacterial detection (BD)⁴–⁶
  o Wastage calculations for pathogen-reduced products are based on shelf-life gained due to avoidance of bacterial culture, and the overall shelf-life of 5 days as per approved US labeling
  o Unit purchase costs:
    • C-PC: $524.00
    • C-PC irradiated: $602.60
    • C-PC serology tested and irradiated: $623.00
    • PR-PC: $625.00
  o 26.3% of PC transfusions are in the outpatient setting (reimbursable via 2017 CMS P- and Q-codes)
  o Adverse events considered were bacteremia and sepsis.⁷–⁸

RESULTS

• Base case annual costs, outpatient reimbursements, and shelf-life results are presented in Table 1.
• In the 100% PR-PC scenario, wastage due to expiration is less than that in the 100% C-PC scenario because, although PR-PC units are more costly, they also have longer shelf-lives. Conversely, wastage due to mishandling is more costly in the 100% PR-PC scenario than in the 100% C-PC scenario due to the greater cost of PR-PC units.
• For all 3 scenarios, the costs of dispensing and transfusion are the same.
• Outpatient reimbursement in the 100% PR-PC scenario is greater than that in the 100% C-PC scenario because CMS reimbursements for PR-PC units are greater than most other PC types.

<table>
<thead>
<tr>
<th>Item Description</th>
<th>100% C-PC</th>
<th>100% PR-PC</th>
<th>75% C-PC / 25% PR-PC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquisition</td>
<td>$4,717,700</td>
<td>$5,102,500</td>
<td>$4,813,900</td>
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<tr>
<td>Secondary bacterial testing including true positives</td>
<td>$131,765</td>
<td>$0</td>
<td>$98,824</td>
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<tr>
<td>Secondary bacterial testing: false positives</td>
<td>$24,241</td>
<td>$0</td>
<td>$18,181</td>
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<td>Wastage due to expiration</td>
<td>$150,698</td>
<td>$122,803</td>
<td>$143,458</td>
</tr>
<tr>
<td>Wastage due to mishandling</td>
<td>$69,944</td>
<td>$75,312</td>
<td>$71,552</td>
</tr>
<tr>
<td>Dispensing and transfusion</td>
<td>$260,721</td>
<td>$260,721</td>
<td>$260,721</td>
</tr>
<tr>
<td>Bacteremia / Sepsis</td>
<td>$36,349</td>
<td>$0</td>
<td>$27,262</td>
</tr>
<tr>
<td>Total hospital cost</td>
<td>$5,391,418</td>
<td>$5,561,336</td>
<td>$5,433,897</td>
</tr>
<tr>
<td>Outpatient reimbursement</td>
<td>$1,012,828</td>
<td>$1,075,363</td>
<td>$1,028,462</td>
</tr>
<tr>
<td>Maximum usable shelf-life (hours)</td>
<td>48.00</td>
<td>63.20</td>
<td>51.80</td>
</tr>
</tbody>
</table>

*Values in this table may differ from those in the submitted abstract because the model was based on an earlier version of the model, whereas these base-case results are derived from the final model.

LIMITATIONS

• Benefits not captured by the model include mitigation of transfusion-transmitted graft vs. host disease due to the inactivation of T-cells, and reduction in transfusion transmitted infectious risk from viruses and protozoa such as emerging pathogens, which may impact cost/benefit analyses.
• Not all hospital survey respondents were tracking data for all questions on the survey, resulting in small sample size; therefore, some survey responses were based on published, peer reviewed literature or expert opinion.
• 7-day C-PC with PGD, associated FDA registration, and labeling/inventory related costs not considered.
  o To be considered in future version of the model.
• Durable equipment costs excluded.
  o The model compares “apples to apples” – that is, assuming infrastructure is in place, the model looks at how the costs for C-PC with or without RT vs PR-PC compare.
• Startup costs (e.g., cost of equipment and training) of onboarding either secondary bacterial testing technology or pathogen-reduction technology at a hospital are not included in the model.

CONCLUSION

• The model predicts a modest (2.5%) increase in net costs for PR-PC compared to C-PC depending on the degree of PRT conversion; this takes into account cost offsets such as elimination of BD and irradiation, decreased waste due to increased shelf-life, and outpatient reimbursement.
  o This represents a small percentage increase associated with using PR-PC when considering the overall annual blood budget
• The effective PC shelf-life is potentially increased with PR due to elimination of BD, and is dependent on nucleic acid testing turnaround time.
  o This model can serve as an important tool for hospitals considering PR adoption.

REFERENCES

7. Mean cost per case for index hospitalization. Derived from the Healthcare Cost and Utilization Project (HCUP); http://hcupnet.ahrq.gov/ for 2014 and inflated to SUS 2015 using the Consumer Price Index for medical cost inflation [https://www.bls.gov/cpi/].

FUNDING DISCLOSURE

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