**INTRODUCTION**

- Platelet production (PP) and platelet administration (PA) are complex processes, largely due to pathogen testing.
- Pathogen reduction (PR) is a new technology that has the potential to improve PP efficiency by simplifying these processes.¹
- PR has successfully been used in Europe for over 10 years.
- Changing FDA guidance may increase uptake of PR in the US (Table 1).²³
  - Recent Food and Drug Administration (FDA) guidance, prompted by Zika virus concerns, recommends either PR or additional Zika testing for platelets manufactured in the US.³

**OBJECTIVES**

- To develop a framework detailing the tasks involved in PP and PA from the hospital perspective.
- To use this framework to assess the potential impact of PR on PP and PA tasks.

**METHODS**

- Identification of tasks involved in producing and administering conventionally processed (CP) and PR platelets was informed through direct observation of these tasks at a hospital blood donor center as well as discussion with clinical experts and prior work.⁴
- Potential impacts of PR vs. CP on PP and PA tasks were identified.

**RESULTS**

- Major PP tasks include donor recruitment, apheresis donation, processing, and storage.
  - PP comprises 26 tasks for both CP and PR platelets.
  - Storage of CP platelets requires point-of-issue (POI) bacterial testing of platelets every 24 hours for units aged 4 days and older.
- Major PA tasks include physician ordering, administration to patient, and adverse event (AE) monitoring and management (both infectious and noninfectious AE).
  - PR comprises 13 tasks with conventional platelets vs. 12 tasks with PR platelets.
  - POI is task-intensive, requiring up to 6 additional steps per test repeated every 24 hours, ranging from 2-6 tests per unit depending on platelet age.
- Potential impacts of PR on PP and PA tasks from the hospital production perspective are presented in Fig. 1.
  - Noninfectious AE tasks are similar for both PA and PR platelets; however, infectious AE are expected to be reduced or eliminated with PR.
  - Large-scale epidemiological databases are needed to inform potential impacts of PR on AE rates.

**LIMITATIONS**

- This analysis takes the US perspective only and does not draw on European experience.
- Process framework was developed in a time of changing FDA guidance.
- Relative impact of PR is likely to depend on hospital characteristics (e.g., size, specialty).

**CONCLUSIONS**

- The PP framework can be used in hospital operations research to understand the PP and PA processes and potential impacts of changing FDA guidance.
- PR may simplify tasks involved in producing, storing, and ordering platelets.
- This framework can be used to inform an economic model comparing CP to PR.

**REFERENCES**


**FUNDING DISCLOSURE**

Unfunded preliminary research to inform subsequent work for Cerus Corp.

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**Figure 1. Potential Impacts of PR vs. CP on PP and PA Tasks**

<table>
<thead>
<tr>
<th>Date of Release</th>
<th>Report Title</th>
<th>Key Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2016</td>
<td>Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry²</td>
<td>- FDA has approved PR technology for use in lieu of bacterial culture and rapid bacterial testing of platelets in the US. - PR platelets have a shelf life of 5 days. - CP platelets have a shelf life of 5 days with the use of rapid bacterial testing (POI) performed every 24 hours starting on Day 4. - Shelf life of both PR and CP platelets can be extended to 7 days using specific 7-day storage containers and bacterial testing via either POI on Days 6 and 7 or culture on Days 4 or 5.</td>
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<td>Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry³</td>
<td>- As of February 2016, FDA recommended Zika testing only for those blood products donated in certain locations considered to be “active” for Zika virus transmission in the US. - FDA now recommends Zika testing for all donated blood products nationally. - PR may be used in lieu of Zika testing for platelets.</td>
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**Table 1. Summary of Recent FDA Guidance on Platelet Processing**

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