

Logistical Management of the Incorporation of Pathogen Reduced Single Donor Platelets (PR-SDP) into Inventory at a U.S. Tertiary Care Medical Center



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Background: The approval of PR-SDP by the FDA provided an opportunity to improve the safety of our platelet inventory across all patient demographics (Fig 1). We outline our approach and address issues faced during the first 4 months of PR-SDP availability.

Study Design/Methods: Our nursing education team provided presentations to the nursing and clinical unit support staff. A company-sponsored trainer staffed sessions for the evening/night shifts on the clinical wards. Presentations to physicians were made by the blood bank medical staff. Information Technology personnel created a new product type in the blood bank computer system, tested the ABO/Rh truth tables, and ensured that billing codes were in place. The necessity for transiently supporting a dual inventory of PR-SDP and conventional platelets led to consultation with the ethics committee and risk management, to confirm that PR-SDP and conventional platelets (C-PLTs) tested for bacteria (“safety measure” testing) could both be considered the hospital standard of care (Fig 2). We chose to not gamma irradiate any unit of PR-SDP, consistent with the package insert.

Figure 1: Patients Receiving PR Platelets

Adults in General Med-Surg Population
 Oncology/Transplant
 Dialysis
 Geriatrics
 Pediatrics
 Pregnancy
 Nursing Moms
 ECMO Patients
 Neonatal/Premies
 Jehovah’s Witnesses - no

Results/Findings: The ethics committee and risk management agreed that informed consent was not needed for transfusion of PR-SDP. PR-SDP available from our blood supplier incremented monthly. Over the first four months of PR-SDP availability, 777 PR-SDP were transfused at our hospital (out of a total of 3286 platelets transfused). After 4 months of scale-up, PR-SDP were approximately 30% of inventory. Questions received during the nursing and medical conferences related to: the risk of bacterial contamination with C-PLTs vs. PR-SDP; toxicology of the PR process; scanning PR-SDP labels into the electronic medical record; and the need to irradiate PR-SDP. Our use of a “safety measure” addressed concern over bacterial contamination of C-PLTs. Published PR-SDP toxicology data comparing the content of psoralens in food products such as grapefruit (~12 mg per 100g) to the content in PR-SDP (<1 ng per mL) addressed toxicology concerns. IT allayed Nursing’s concern over scanning issues with a simple demonstration. Finally, we ensured that all parties were aware that FDA did not require irradiation of PR-SDP. Presentations at the medical conferences were also used as an opportunity to provide transfusion-transmitted disease training and information on platelet utilization. Company personnel did not present at medical or nursing conferences per institutional policy. No complaints were received following the PR-SDP roll-out despite the presence of a dual inventory.

**COPING WITH A DUAL INVENTORY:
 PROPOSED SOLUTION**

PR = CP + SM

PR = pathogen reduced plts
 CP = conventional plts
 SM = Safety measure (verax)

Concept is: PR plts and CP+verax are BOTH considered S.O.C.

Conclusion: Using an inclusive approach to staff training, PR-SDP can be seamlessly added to the blood bank inventory.

Fig 3: Approval of PR Platelets Coming into YNH

- Internal BB consensus to move forward
- Switch 100% - becomes SOC; no informed consent
- Discuss with Dept. Chair
- Discuss with Laboratory Manager
- Discuss with Risk Management
- Discuss with IT Section (EPIC/Soft Bank)
- Discuss with Blood Supplier(s)
- Approval of Transfusion Committee
- Discuss with Physicians/Nurses/LIPs
- Present to Ethics Committee
- Discuss with YNHHS Medical Officers and Administration
- Work with Finance Dept; Business Plan
- Approval of C-Suite ---- CMO(s) and CEO(s)
- Approval of Medical Board

References:

- Amato M., et al. Impact of platelet pathogen inactivation on blood component utilization and patient safety in a large Austrian Regional Medical Center. *Vox Sang* 2017;112 (1):47–55
- Rebullia P., et al. Clinical effectiveness of platelets in additive solution treated with two commercial pathogen-reduction technologies. *Transfusion* 2017;57:1171-83.
- Li JW., et al. Addressing the risk of bacterial contamination in platelets: a hospital economic perspective. *Transfusion* 2017; doi:10.1111/trf.14216
- Osselaer JC., et al. Universal adoption of pathogen inactivation of platelet components: impact on platelet and red blood cell component use. *Transfusion* 2009;49:1412-1422