

# Phased Implementation of Pathogen-Reduced Platelets in a Health System

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## Background

Pathogen-reduced platelets (PRP) provide improved safety compared to conventional apheresis platelets, but collection and manufacturing are complex. Early evidence shows only 40-45% of double platelet collections meet requirements for pathogen reduction treatment.<sup>1</sup> Blood centers need hospitals to implement PRP to start manufacturing, but hospitals may not wish to use PRP until they can provide the product to all patients. Scaling up manufacturing at the blood center and phasing in PRP across patient populations meets both parties' needs. We evaluated this strategy at our university health system (transfusion volume: 9,500 apheresis platelets annually), which includes two hospitals (750 inpatient beds) and an outpatient cancer center.

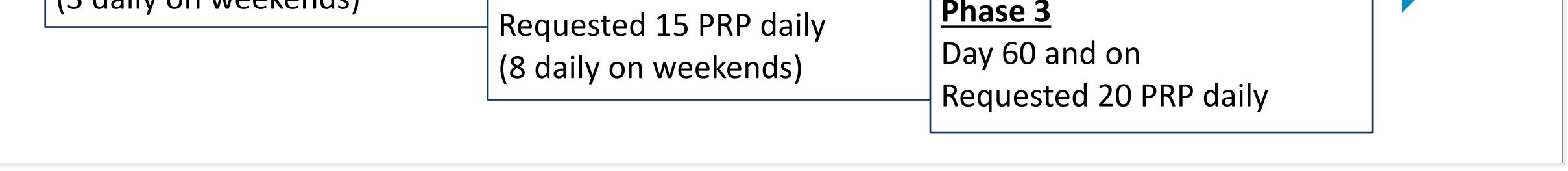
# Phased Implementation Strategy Outpatient cancer center Phase 1 Days 1-45 Requested 5 PRP daily (3 daily on weekends)

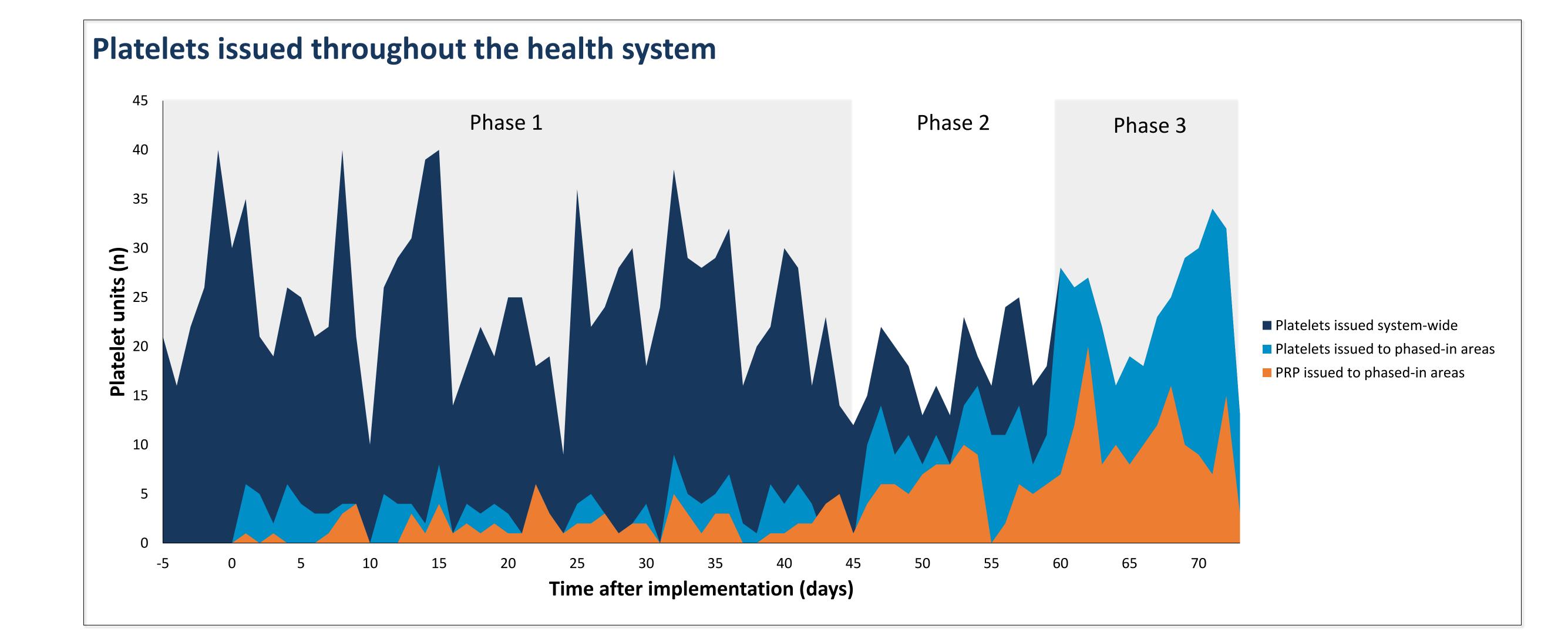
# **Study Design and Methods**

Approval and funding were obtained from hospital administration, and stakeholder groups were educated and consensus gained. Live training was provided for nurses in the outpatient cancer center (week 0) and the bone marrow transplant (BMT) ward (week 6). An e-mail communication explained the change to all physicians and nurses. In Phase 1, we implemented PRP in the outpatient cancer center. These patients are immunocompromised and do not have access to the immediate advanced critical care of the inpatient environment should a septic reaction occur. In Phase 2, we expanded usage to include the inpatient BMT ward. In Phase 3, we lifted all restrictions so PRP could be used throughout the health system, with the goal to reach 100% PRP within 6 months.

### Results

In Phase 1 (weeks 1-6), we requested 31 PRP products weekly, our blood supplier provided an average of 23 PRP weekly (range 9-33), and PRP constituted 44% of platelet transfusions in the cancer center. In week 2, excess PRP inventory required use in the inpatient BMT ward ahead of schedule, a practice which continued throughout Phase 1. In Phase 2 (weeks 7-8), we formally expanded issuing of PRP to include the inpatient BMT ward and requested 91 PRP products weekly. Our blood supplier provided an average of 57 PRP weekly (range 44-69), and PRP constituted 53% of platelet transfusions in the phased-in areas. In Phase 3 (weeks 9-10), we began issuing PRP throughout the health system. Our supplier provided an average of 70 PRP weekly (range 61-78), and PRP constituted 43% of all platelet transfusions. Scaling-up is ongoing.





# Conclusion

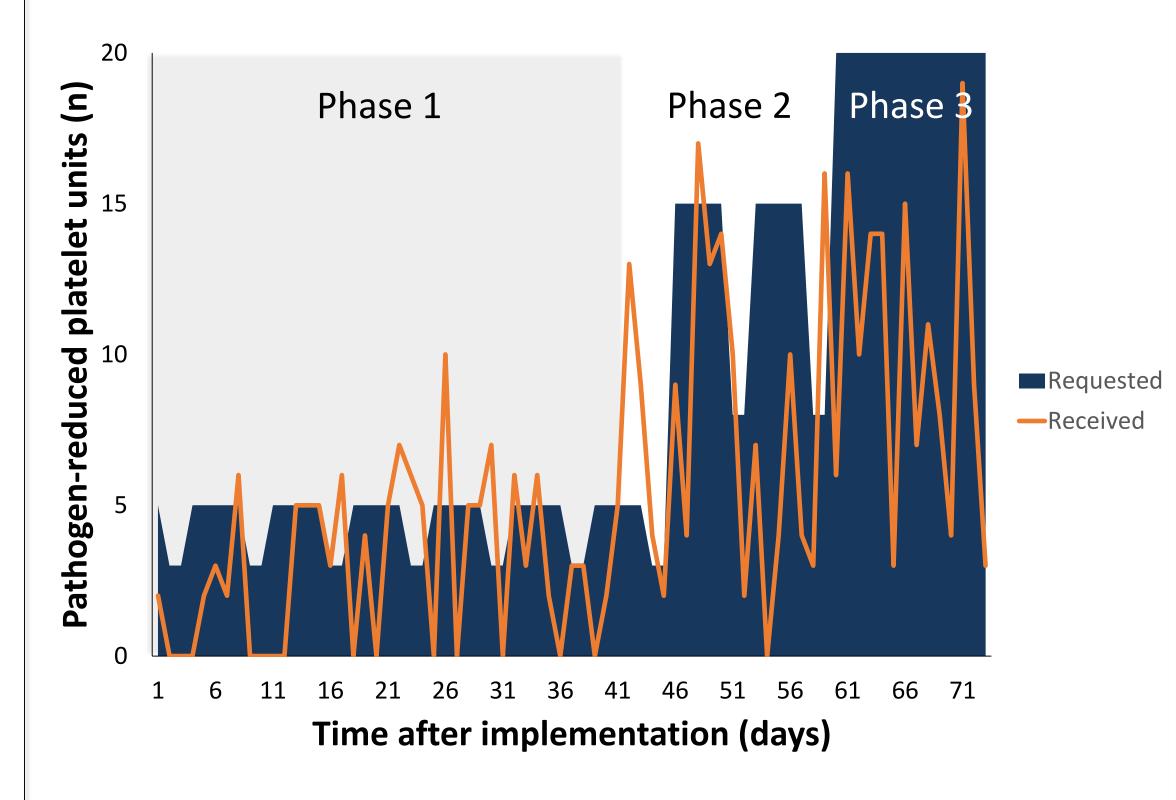
Phased implementation of PRP by patient group prioritizes patients who stand to benefit most from the product, and allows time for the blood center to scale up manufacturing. Flexibility to use PRP in different areas is needed to accommodate variations in number of transfusions. Physicians, nurses, and staff have been receptive to the change, and no complaints have been received.

#### References

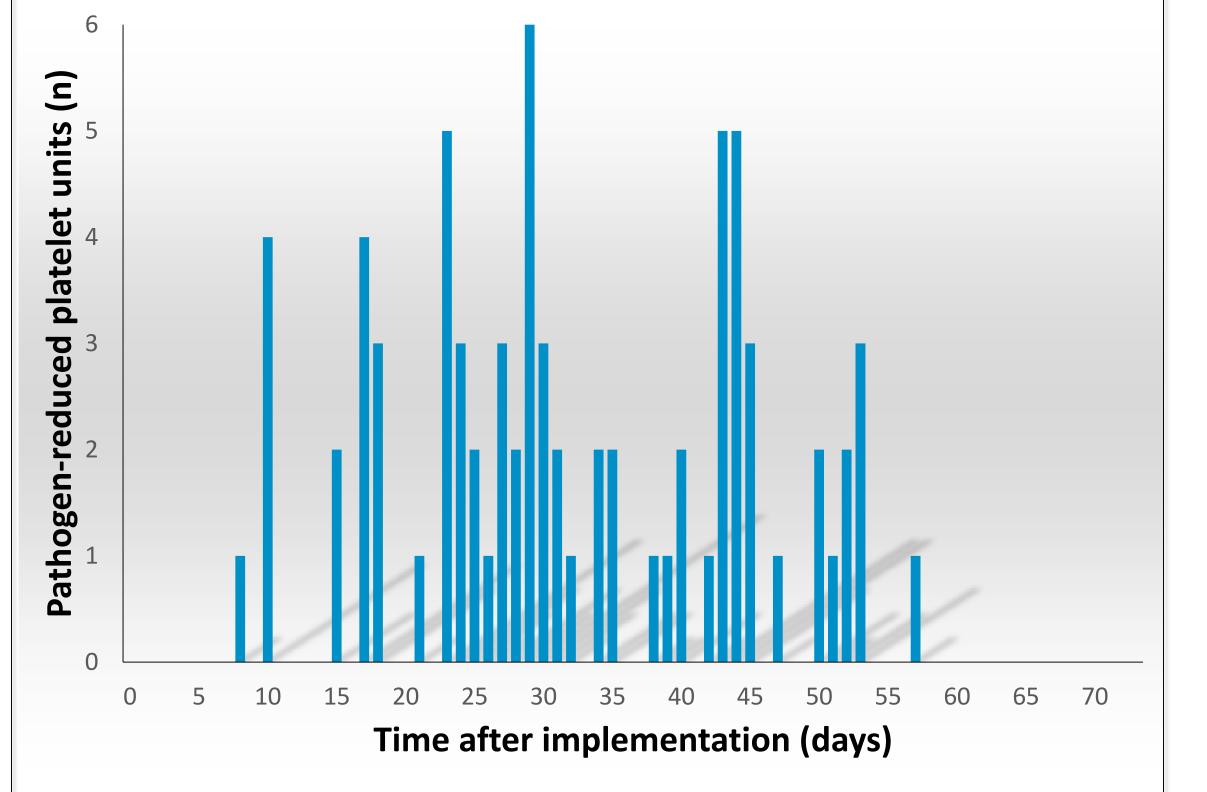
[1] AABB, America's Blood Centers, American Red Cross. Comments regarding Docket No. FDA–2014–D– 1814. April 12, 2017.

# Key point: Phased implementation is a

Pathogen-reduced platelets requested and received from the blood center



# Pathogen-reduced platelets issued to areas not yet phased in



# practical and ethical way to introduce

## pathogen-reduced platelets.

**PRP supplied by the blood center.** The blood center's ability to supply the requested number of PRP varied, emphasizing the challenges of collection. Blood centers likely need extensive practice before they can reliably meet targets, illustrating the importance of the phased implementation

strategy .

**Protocol deviations.** During phases 1 and 2, an average of 1.3 PRP (SD 1.6, range 0-6) were issued to non-phased-in areas daily. Number of transfusions in the phased-in areas varied, and the flexibility to use PRP in other areas of the health system avoided wastage and brought safer products to more patients.