



Advancing Transfusion and
Cellular Therapies Worldwide

2017 Platelet Bacterial Risk Control Survey November 2017

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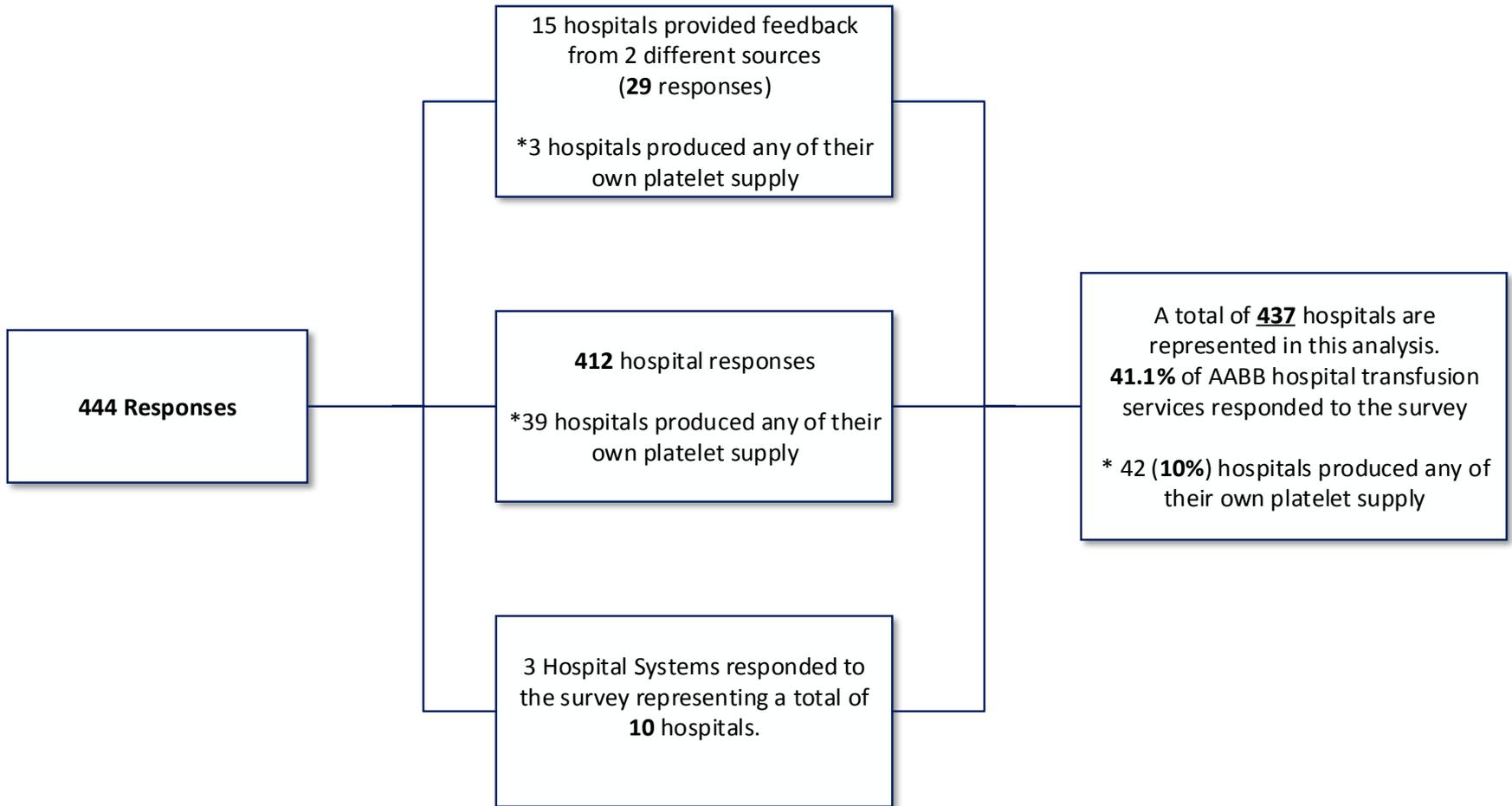
Objective

- To determine the level of understanding and preparedness for the draft bacterial guidance, AABB conducted a survey of medical directors and accreditation contacts in member transfusion services
 - An electronic survey was distributed from June 19th to July 21st, 2017
 - Participants were asked questions to determine:
 - Their understanding and preparedness to implement the FDA's guidance
 - The appropriate education programs and resources to support AABB's membership upon the implementation of the guidance
 - These data will not be presented today.

Executive Summary of Survey Results

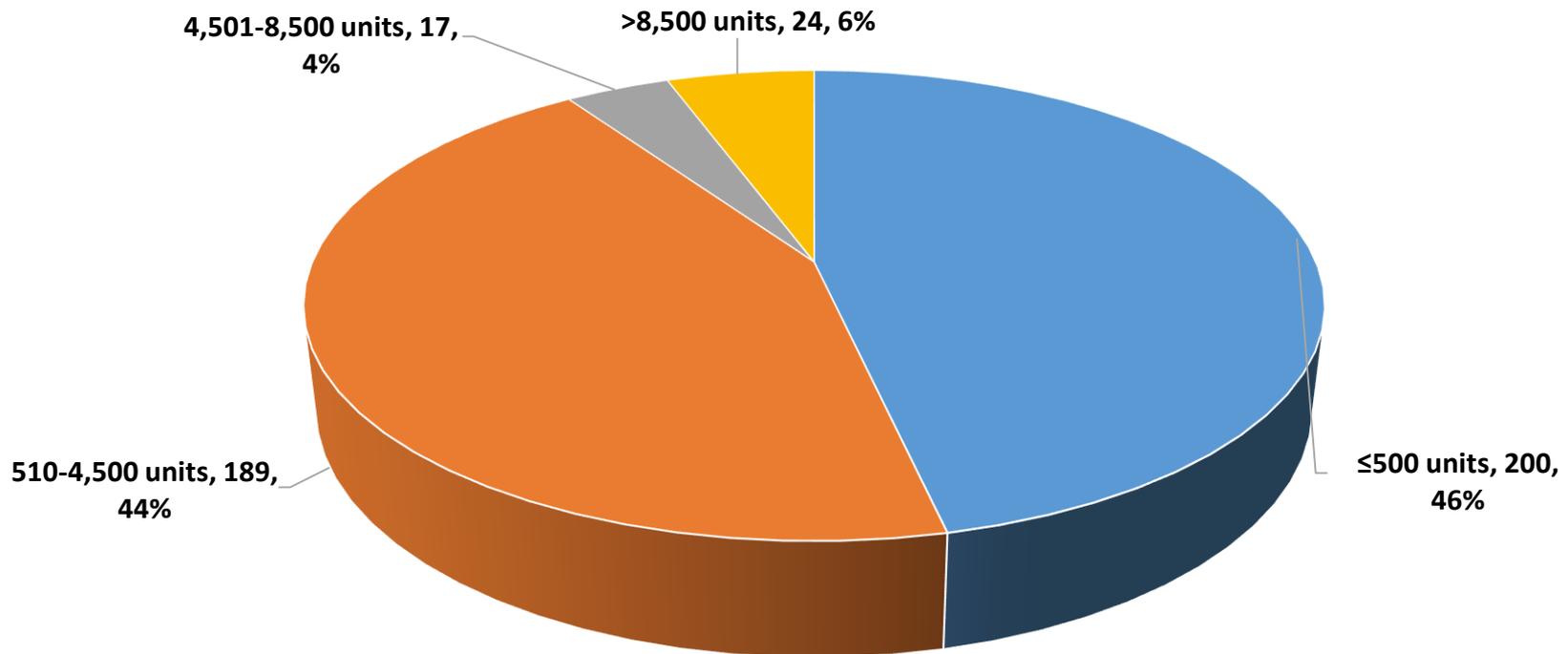
- The survey response rate was 41.4% of AABB hospital member transfusion services.
- 94% of respondents were knowledgeable of the draft guidance.
- 75% of respondents are preparing for implementation of the final guidance.
- 59% anticipate challenges in implementing the draft guidance.
- Most hospitals (59%) plan to implement a combination of risk mitigation strategies.
- When asked which bacterial risk control methods they intend to implement,
 - 69% of respondents indicated that pathogen inactivated (PI) SDPs are a part of their implementation plan.
 - 20% of responding hospitals (15% of transfused platelets represented by the survey) indicated a plan that **only** includes PI SDPs.
 - 45% of respondents plan to use an FDA cleared rapid test on days 4 and/or 5 as part of their implementation plan.
 - 26% plan to transfuse platelets only on days 1-3 as part of their implementation plan.
 - 17 (4%) responding hospitals indicated a plan that **only** includes transfusing day 1-3 platelets; all these hospitals transfused <1,200 SDPs in 2016.

Data Collection

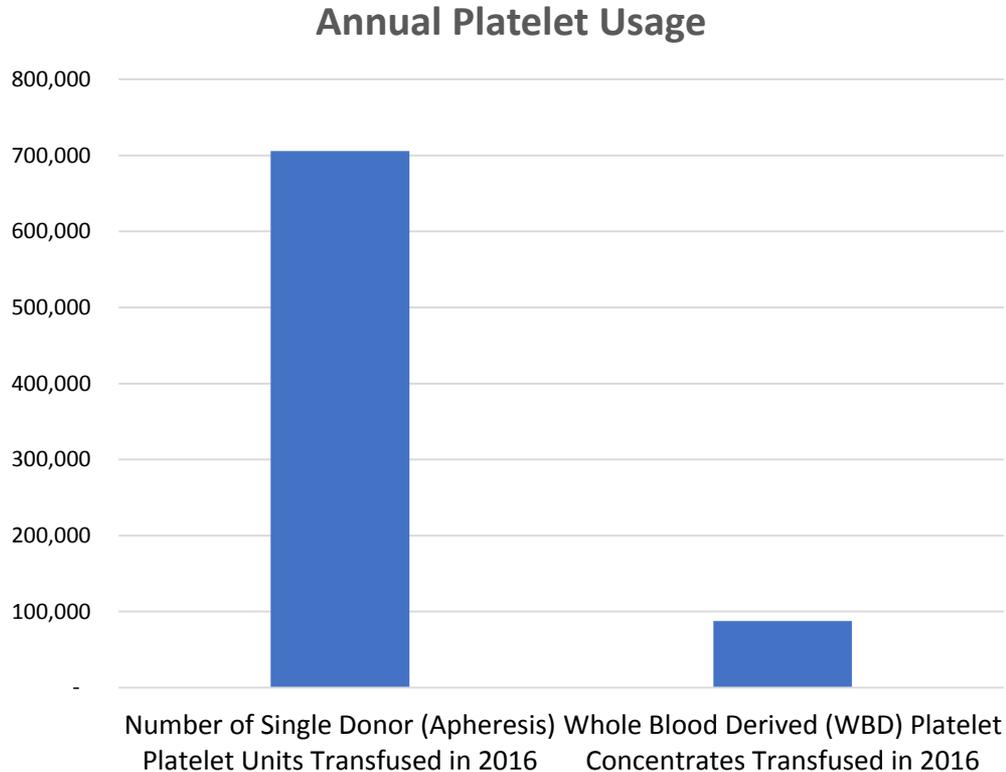


Distribution of Responding Hospitals by Annual Apheresis Platelet Usage

Numbers of Responding Hospitals by Annual Apheresis Platelet (SDP) Usage



2016 Total Annual Platelet Usage



- A total of 705,912 Single Donor Apheresis Platelet units and 87,642* (404,320 single concentrates) WBD platelets were transfused by responding hospitals in 2016.
- The number of single units in each WBD platelet pooled ranged from 1 to 10 units. The average number of units in each pool was 5 units.

* WBD platelets expressed as apheresis equivalents.



NBCUS 2015 Platelet Results

Assuming similar SDP transfusions in 2015 and 2016, survey respondents transfused 39.1% of the NBCUS SDPs total

Total Platelets Distributed

- 2,436,000
 - (95% CI, 2,230,000-2,42,000)
- Apheresis Platelets 2,234,000
- WBD Platelets 202,000

Total Platelets Transfused

- 1,983,000
 - (95% CI, 1,816,000-2,151,000)
- Apheresis Platelets 1,807,000
- WBD Platelets 171,000

- 13.1% fewer platelet transfusions in 2015 than in 2013
 - Apheresis declined by 15.4%
 - WBDP increased by 33.7%

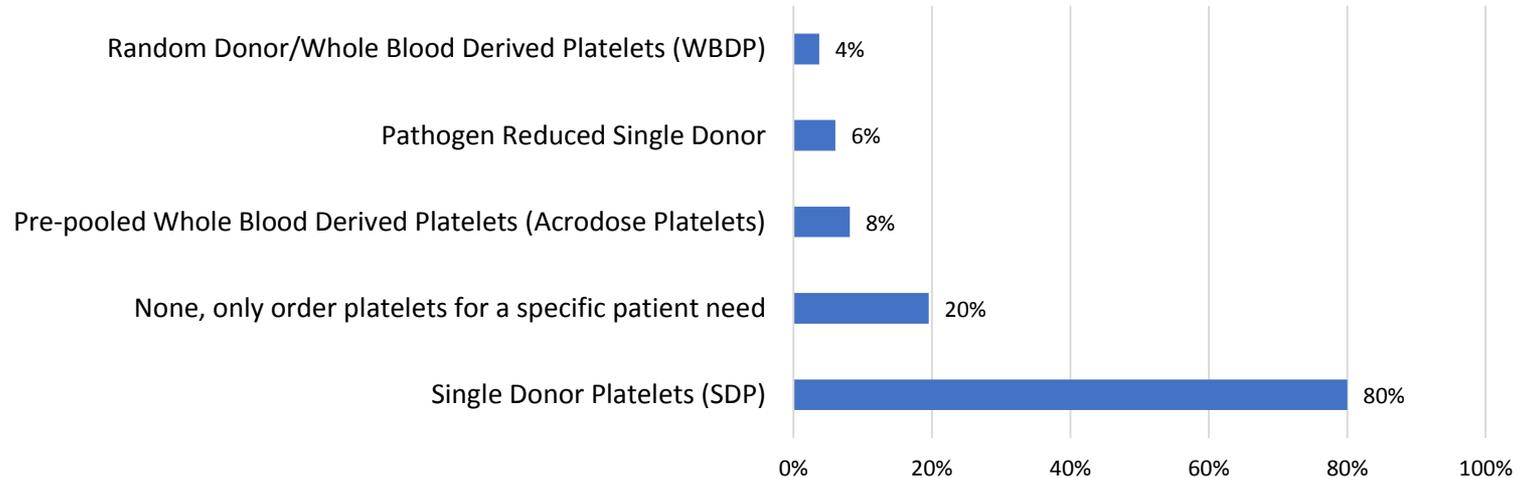
Ellingson KD, Sapiano MRP, et al. Continued decline in blood collection and transfusion in the United States- 2015. *Transfusion* 2017;57:1588-1598.



Platelet Supply: Types Routinely Stocked

What types of platelet product(s) do you routinely stock? Please choose all that apply.

Types of Platelet Products



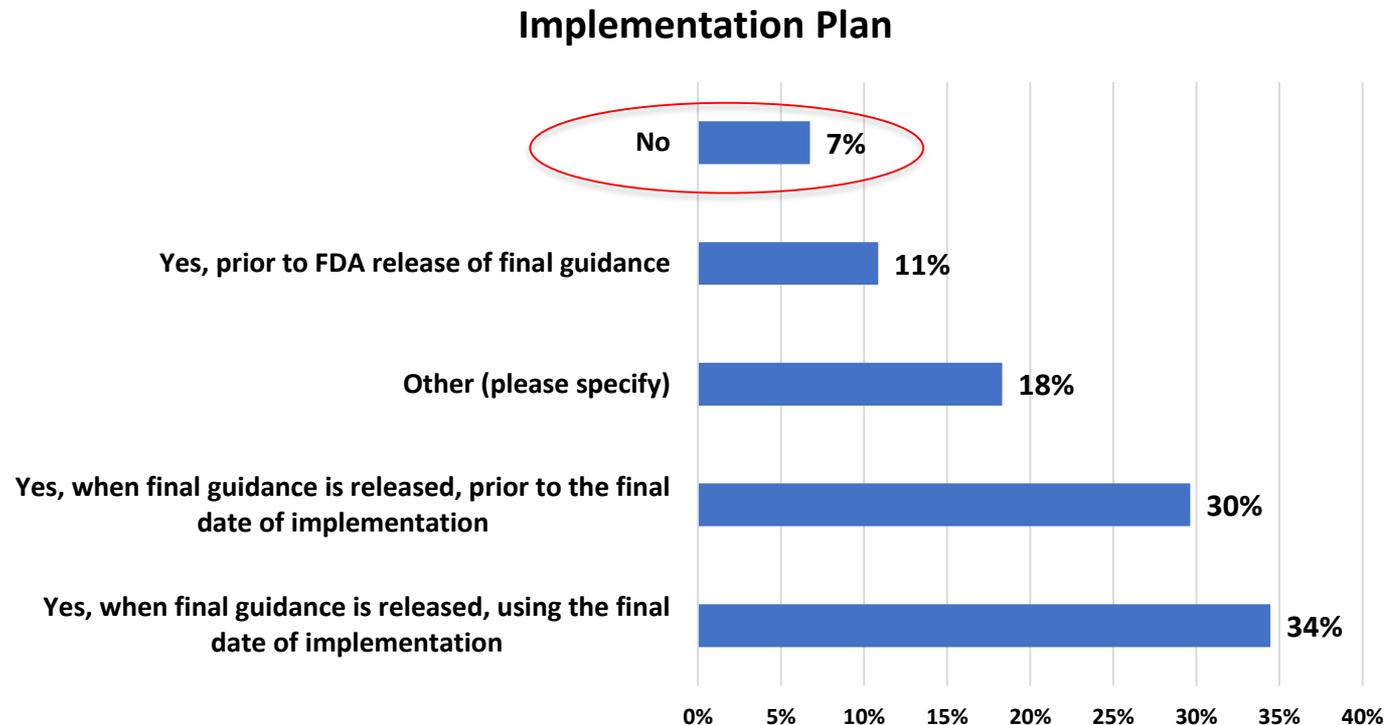
- Single Donor Platelet units are the most common type of platelet products routinely stocked.

AABB Hospital Awareness of FDA Draft Guidance

- 98% of respondents are aware that there are different strategies to mitigate the risk of bacterial contamination in platelets.
- 94% of respondents are aware of the recommendations in the March 2016 FDA draft guidance on minimizing the risk of bacteria in platelets.

Timing of Planned Implementation

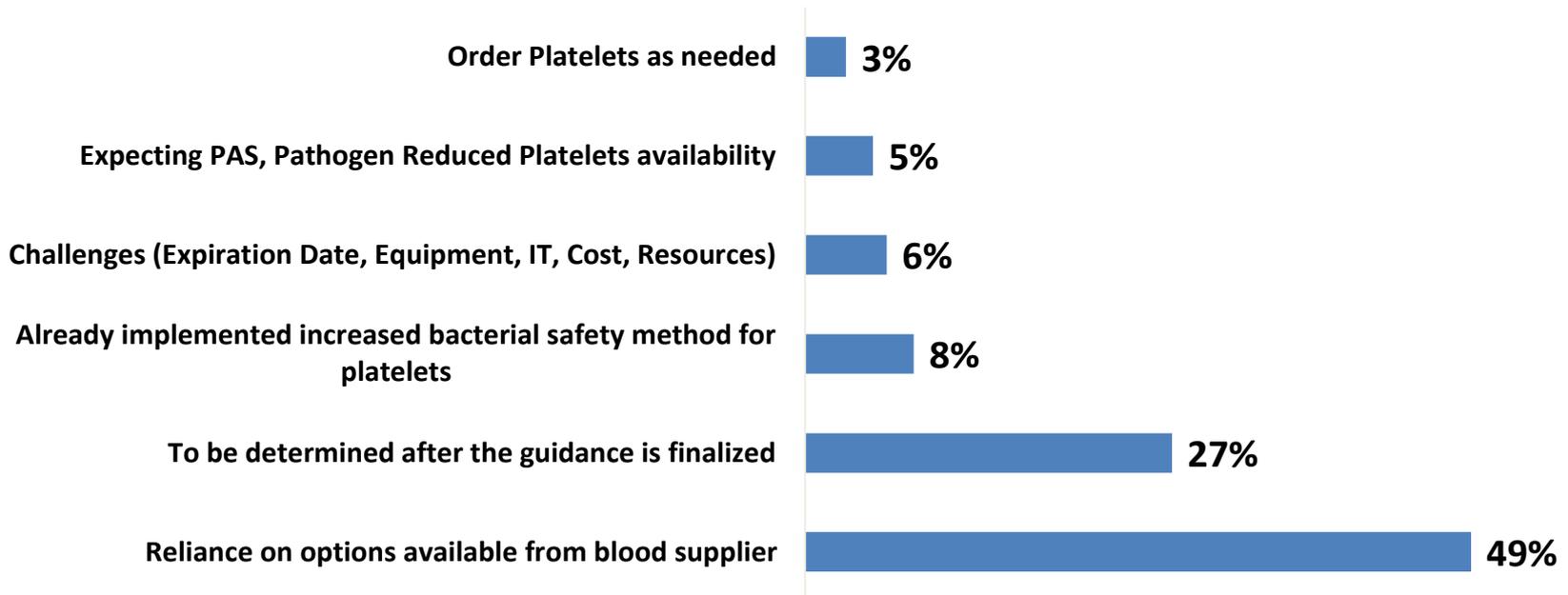
Are you preparing to implement the recommendations based on the draft guidance?



“Other” Implementation Plans

Are you preparing to implement the recommendations based on the draft guidance? Other (Specify)

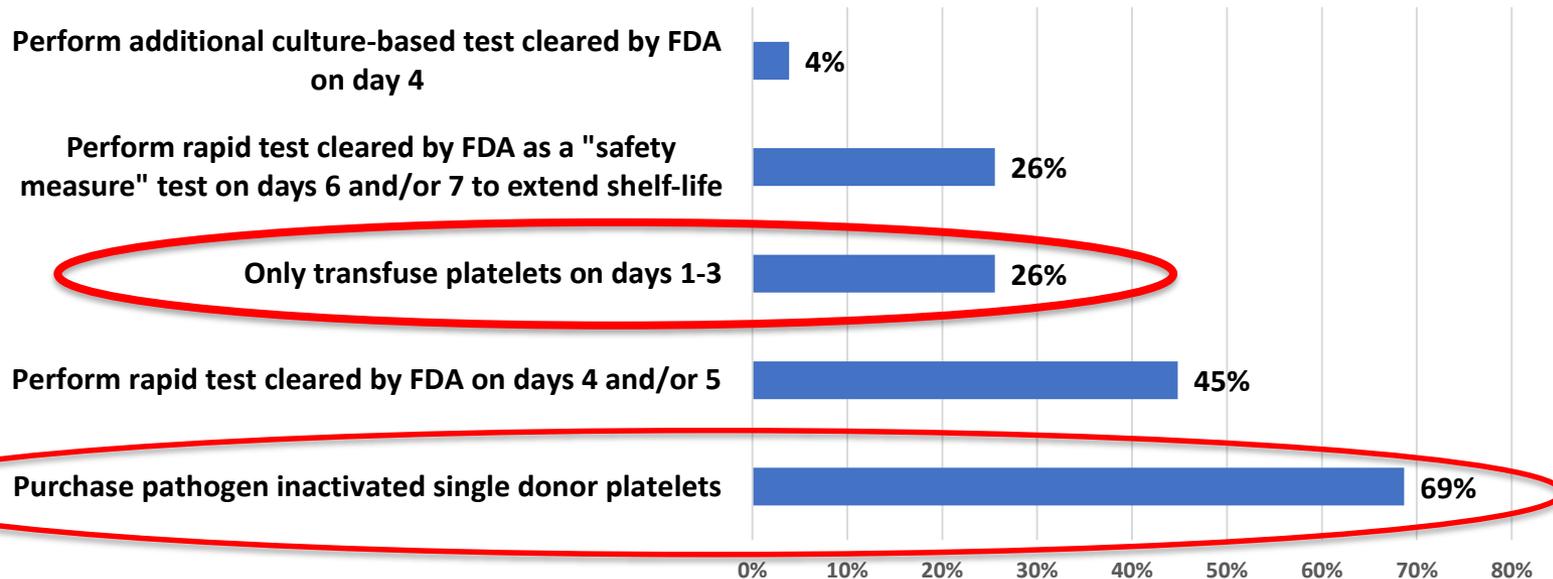
Preparing to Implement FDA Recommendations (n=77)



Risk Mitigation Approach Planning

Which choice(s) might you implement? Please choose all that apply.

Implementation



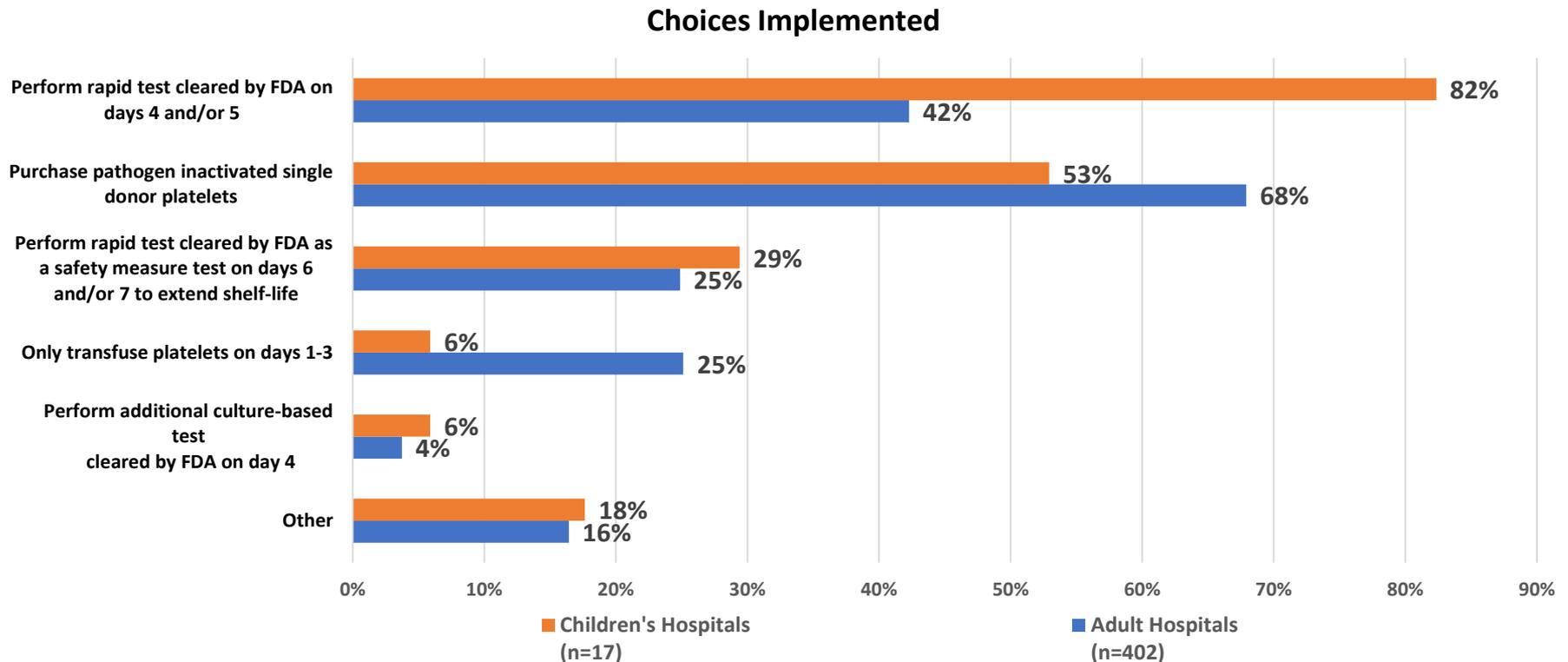
Risk Mitigation Approach Planning

- More than half of responding hospitals (59%) indicated that they would choose two or more risk mitigation methods.
- The remaining 32% of hospitals that only chose a single risk mitigation method specified*:
 - 20% PI SDP only (105,000 SDP)
 - 4% FDA cleared rapid test on days 4 and/or 5 only (20,000 SDP)
 - 4% Transfuse platelets on days 1-3 only (3,000 SDP)
 - 3% FDA cleared rapid test as a safety measure on days 6 and/or 7 to extend shelf life only (27,000 SDP)
 - <0.1% Perform additional culture based test on day 4 only (22,000)
- 9% of responding hospitals didn't select any mitigation option
 - These hospitals are expecting blood suppliers to implement changes, are assessing the most cost effective options, or are awaiting for FDA release of final guidance.
- The impact of these choices varied by the size of hospital platelet transfusion service.



Which Bacterial Risk Mitigation choice(s) might you implement? Children's vs Adult's Hospitals

Which choice(s) might you implement? Please choose all that apply.

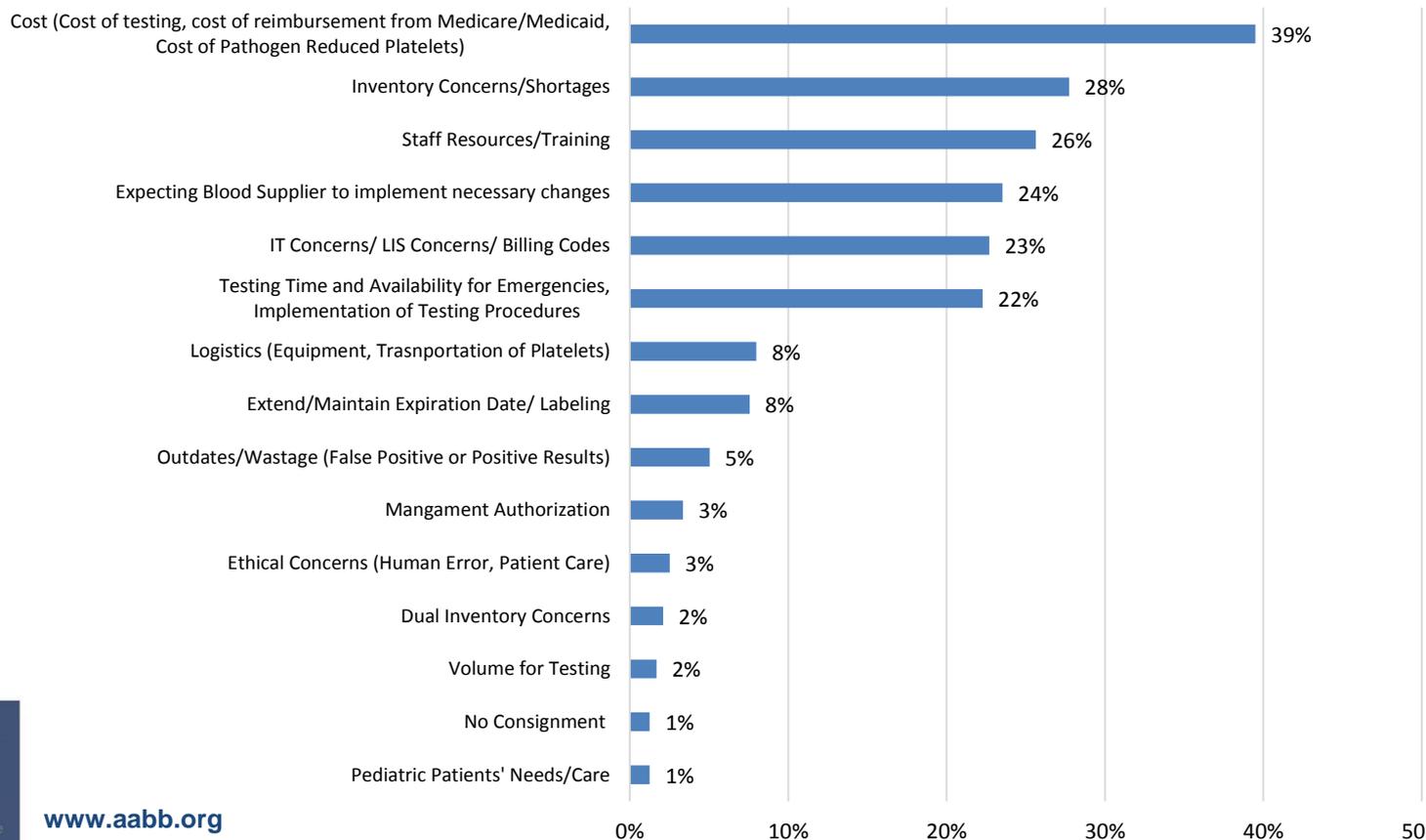


- 76% of Children's hospitals chose 2 or more risk mitigation strategies vs. 56% of adult hospitals.

Challenges of Implementation

- 59% of respondents anticipate challenges for implementation of the draft guidance in their institution

Challenges for Implementation (n=238)



Conclusions

- Respondents to the 2017 Platelet Bacterial Risk Control Survey represent 41% of AABB transfusion service facilities transfusing an estimate of 39% of transfused platelets .
 - Only 10% produce any of their own platelet supply and the majority of them (80%) routinely stock single donor platelets
- Facilities are well aware of different strategies to mitigate the risk of bacterial contamination in platelets (98%) and have knowledge of the recommendation to minimize the risk of bacteria in platelets (94%).

Conclusions

- Overall, hospitals are preparing to implement the recommendations when the final guidance is released (34% using the final implementation date and 30% prior to the final date of implementation).
- Only 32% of responding hospitals plan to implement a single mitigation option.
- Most hospitals plan to implement some combination of the following:
 - Purchasing pathogen-inactivated single donor platelets (69%),
 - Performing FDA cleared rapid test on days 4 and/or 5 (45%),
 - Performing FDA cleared rapid test as a safety measure on days 6 and/or 7 to extend shelf life (26%)
 - Only transfusing platelets on days 1-3 (26%).
- Most hospitals (59%) anticipate challenges in meeting guidance requirements and rely on blood centers to provide products.
- Based on the number and size of hospitals that indicated they would implement PI SDPs only, PI SDP demand is expected to be a minimum of 269,000* units per year.

* Extrapolated PI SDP units using NBCUS total Apheresis Platelets Transfused in 2015.





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Thank You

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