# Limiting and Detecting Bacteria in Platelet Products:

## The Red Cross Experience

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# The purposes of the presentation are to review:

- how the Red Cross is meeting AABB Standard 5.1.5.1
- implementation challenges and status after 5 weeks of experience
- early results of testing for bacteria in single donor platelets (apheresis)
- impact on platelet inventory and availability

# Red Cross Decisions

Strategies for limiting bacterial contamination of platelets:

- Platelet collection by apheresis
- Improved arm scrub (Chlorhexidine)
- “Sample first” technology

# Red Cross Decisions

Strategies for detecting bacterial contamination in platelets:

- Automated detection system in 35 locations for single donor (apheresis) platelets
- No testing of random donor (whole blood derived) platelets
- Monitor customer preferences and new technology options (pooled platelets)

# Rationale for Testing 100% of Single Donor (Apheresis) Platelets

- Meet AABB Standard 5.1.5.1
- Potentially increase safety of single donor platelet products
- Automated system available for use
- Standardized single donor platelet inventory
- Customer demand exists

# Rationale for not testing random donor (whole blood) platelets

- Operationally challenging to test large numbers of units
- Better safeguard to test immediately before use at the “bedside”
- Expensive: would increase customer cost by nearly 40%
- Reduces available platelet dose/bag

# Selection of Automated Testing System (Method A)

- High sensitivity
- Proven track record in clinical setting
- Ease of use/high degree of automation
- Cost (approximately $22 per single donor platelet)

# Operating Parameters
# Method A

- Original collection bag sampled before “splits” prepared
- Use aerobic bottle only (one per collection)
- Inoculate after 24 hour hold at 20-24C
- Incubate 12 hours before product labeling for release
- Continue incubation through expiration date

# Actions for Suspect Positive Results

- Dispose of platelet product in inventory or recall product if released
- Notify physician if product previously transfused
- Dispose/withdraw co-components (red cells, plasma)
- Identify organism if product was transfused
- Place donor under surveillance
- Medically evaluate, if donor is culture positive more than once

# Hospital Notification

Letter #1 (11/17/03)

- March 1, 2004 target to culture all SDP
- Approximate $25 increase in cost
- Reduced shelf life (0.5-1.0 days)
- Plans for notification if positive culture results
- Plans for limiting bacteria in RDP

# Hospital Notification, cont…

Letter #2 (12/30/03)

- Confirmed $22 increase in cost
- No plan to test RDP – hospital responsibility

Letter #3 (03/09/04)

- Discontinuation of “Sample First” to limit bacteria in RDP due to hemolysis in tubes and products
- Extensive arm scrub continued

# ARC Response to Hospital Testing

If hospital reports a positive culture or gram stain:

- Products presumed contaminated
- Other components from donation discarded
- Deviation filed with FDA

# ARC Response to Hospital Testing, cont…

If hospital reports pH less than 6.2

- Product fails ARC release criteria
- Products potentially contaminated
- Other components from donation discarded
- Deviation filed with FDA

# ARC Response to Hospital Testing, cont…

If hospital reports other (ph 6.2 -7.0, swirl failure)

- Product meets ARC release criteria
- No products or reporting action taken by ARC
- Hospital encouraged to use gram stain and referred to AABB information

# Implementation Challenges
# Method A to detect bacteria in SDP

- Supply challenges
- Start up costs
- Standard Operating Procedures
- Staff training: Apheresis staff, laboratory
- Space for equipment in 35 locations

# Implementation Challenges: "Sample First" technology

- Short time frame – no bags available
- Logistics of conversion to new bag sets from two different vendors
- Collection staff training
- Problems with dilution of testing samples
- Problems with hemolysis
  - Test tubes: interference with ID testing
  - Products: questionable safety risk

# Implementation Challenges: Chlorhexidine for Arm Scrubs

- Used for donors who claim sensitivity to iodine
- Acceptable storage temperature (20 – 25C)
- Mobile collection operations have variable ambient temperatures so unused devices discarded at end of day
- Product losses due to storage out of range exceed 250 donations
- Strategy is to discontinue use and focus on thorough arm scrub

# Impact on Safety

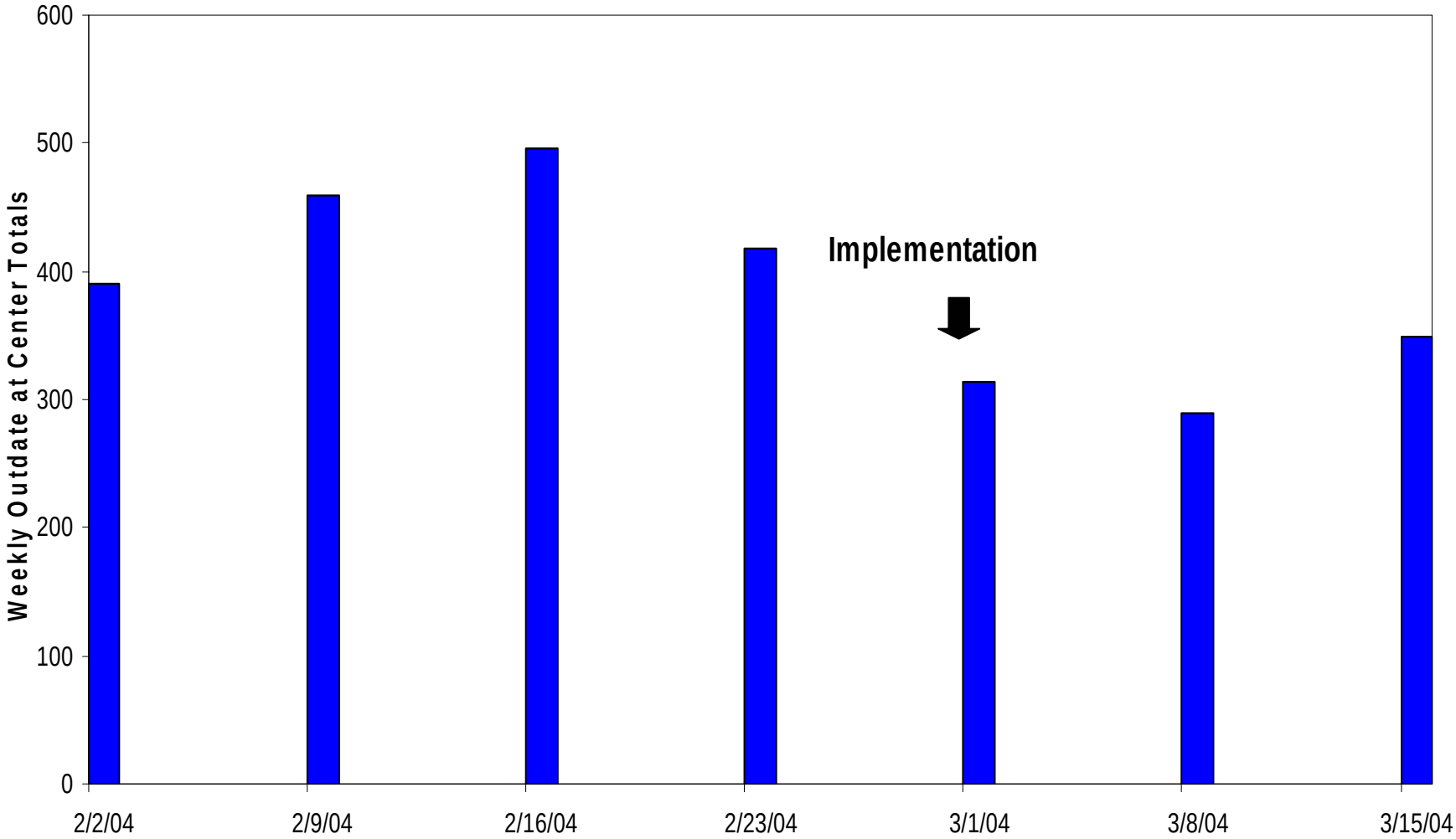
Results of ARC bacterial detection testing (March 1 – March 31, 2004)

- Approximately 39,000 SDP tested
- 27 initial positive results obtained (1:1,400)
- 4 reproducible, true positives (some testing still underway)
  - 2 Staphylococcus
  - 2 Streptococcus
- 6 contaminated products interdicted

# Supply Impact

| Bacterial Detection Testing | Average Four Weeks Prior to Implementation | Average Three Weeks After Implementation | Change |
|---|---|---|---|
| Total Inventory | 3,067 | 3,308 | +7.9% |
| Released Inventory | 1,547 | 1,202 | -22.3% |
| Work-In-Process Inventory | 1,520 | 2,106 | +38.5% |
| Production | 12,203 | 12,143 | -0.5% |
| Customer Shipments | 11,000 | 11,151 | +1.4% |
| Outdates | 441 | 317 | -28.0% |

# Outdates at Center



# Availability Conclusions

- Shortages spread across Tuesday – Friday (previously Tuesday – Thursday)
- More inventory in work-in-process than available due to extended WIP time
- Outdates down because customers are using everything available, including units closer to outdate
- Some regions have shifted to 100% SDP production to avoid conversion to sample first for whole blood collections

# Summary

- Implementation was challenging: decisions have been reversed due to unanticipated problems with new supplies
- Safety:  1:1,400 SDP contaminated (previous estimates were 1:3,000)
- Supply/Availability:
  - longer delays in WIP
  - Shortages spread over more days of the week
  - Customers using all available product so outdates down
- But….we are only 1 month post implementation!