Pathogen Reduction of Platelet Donations as an Alternative Procedure to MSM Donor Deferral

Blood Products Advisory Committee Meeting
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Issues for Discussion

- Discuss the use of pathogen reduction of apheresis platelets as an alternative to the current MSM deferral policy
- Discuss any associated risks and possible mitigations

Outline

- Background
  - FDA approach to blood safety
  - FDA recommendations for MSM donor deferral
- Alternative procedures under 21 CFR 640.120
  - Alternative procedure request
  - Pathogen reduction
- Issues for consideration

FDA Approach to Blood Safety

Consists of multi-layered protections for donated blood

- Donor education and screening [21 CFR 630.10]
- Donation testing [21 CFR 610.40(a)]
- Donor deferral lists [21 CFR 606.160(b)(ii)]
- Quarantine, recall and lookback [21 CFR 630.30]
- Problems and Deficiencies [21 CFR 606.171]

Current FDA Recommendations for HIV risk deferrals

- Donor deferral recommendations for HIV risk apply to all collections, even if the components will be pathogen reduced
- Recommendations for donor deferral include the following, among others:
  - Defer for 12 months from the most recent contact a man who has had sex with another man during the past 12 months
  - Defer for 12 months from the most recent contact a female who has had sex during the past 12 months with a man who has had sex with another man in the past 12 months

Alternative Procedures under 21 CFR 640.120

- FDA may issue an exception or alternative to regulatory requirements ("variance") regarding blood, blood components, or blood products

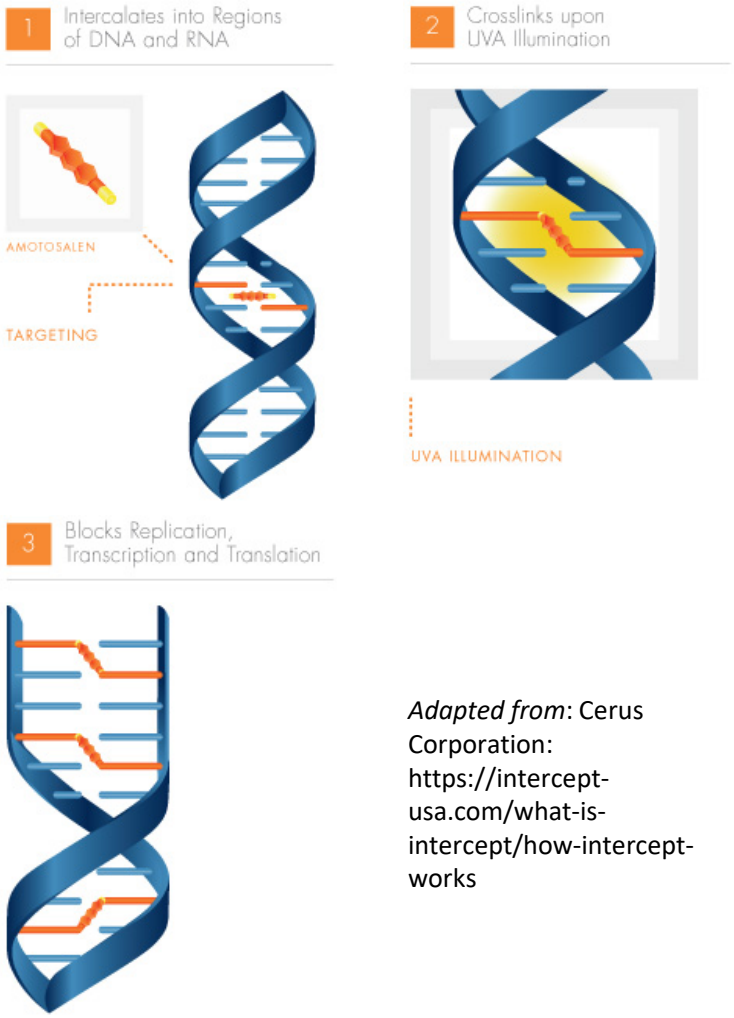
- FDA approval of such exceptions or alternatives are based on the availability of adequate information showing that the alternate process ensures the safety, potency, and purity of the blood component or blood product

Alternative Procedure Request

- FDA has received a request for an alternative procedure to MSM deferral
- Donors will be screened and determined to be otherwise eligible to donate
- Instead of donor deferral, apheresis platelets will be collected and pathogen reduced using an FDA-approved device according to its instructions for use
- Donations will be tested for all relevant transfusion transmitted infections, including HIV, as required by FDA

Pathogen Reduction Technology (PRT)

- One device (INTERCEPT) currently approved by FDA for apheresis platelets and plasma
  - Based on Amotosalen/UVA technology
- Intended to reduce the risk of transfusion-transmitted infection (TTI), including sepsis
- Performed within 24 hours of collection



Adapted from: Cerus Corporation: https://intercept-usa.com/what-is-intercept/how-intercept-works

HIV Viral Reduction with INTERCEPT

Pathogen	Platelets in PAS-3 Log_{10} Reduction (pfu/mL)	Platelets in 100% Plasma Log_{10} Reduction (pfu/mL)
HIV-1 IIIB, cell-associated	≥5.4	≥4.7
HIV-1 IIIB, cell-free	≥5.6	Not tested
HIV-1 Z84 (clinical isolate)	≥3.3	Not tested
HIV-2 CLB-20 (clinical isolate)	≥2.4	Not tested

- Based on input titer and post-treatment titer in 1 mL

Adapted from: INTERCEPT Blood System for Platelets - Dual Storage Set Package Insert, July 17,2018.

Issues for Consideration

- The extent of HIV log reduction to prevent HIV transmission by transfusion
- The possible effect of the variance request on platelet supply
- Manufacturing process for pathogen reduced platelets
  - Controls to prevent process failures
  - Limitation of pathogen reduction to specific platelet platforms

Issues for Consideration (2)

- Processes for managing a dual inventory of pathogen-reduced and untreated components
- Adequate measures to prevent release or distribution errors e.g. use of blood establishment computer systems (BECS)
- The risk and consequences of biological product deviations (e.g., failure to perform pathogen reduction on platelet component collected from a donor not deferred for MSM)

Issues for Discussion

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- Discuss any associated risks and possible mitigations