



American Plasma Users Coalition

MSM Blood Donor Deferral Policy

June 10-11, 2010

Department of Health and Human Services
Advisory Committee on Blood Safety and Availability

A-PLUS Coalition Members



NATIONAL HEMOPHILIA FOUNDATION
for all bleeding and clotting disorders

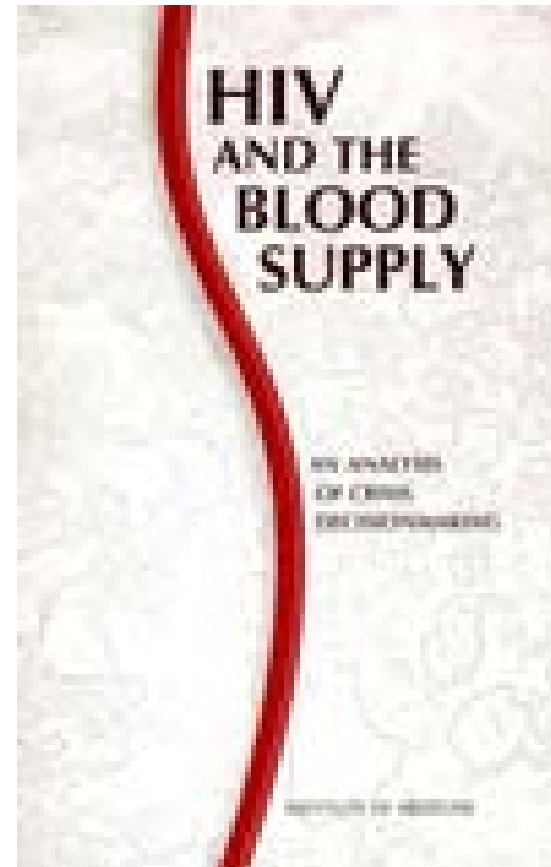


The American Plasma Users Coalition (A-PLUS)
was formerly known as the Plasma User Coalition (PUC)



Stakeholder Participation

The National Academy of Sciences, Institute of Medicine (IOM) Report, *HIV and The Blood Supply: An Analysis of Crisis Decision Making*,” very clearly articulated the need to ensure the participation of all the stakeholders impacted by the blood supply and its regulation.



Framing the Issue

IS NOT SIMPLY ABOUT:

- Blood Supply
- Low Risk
- Discrimination
- HIV only
- MSM
- Hemophilia
- Certainty

IS ABOUT:

- Blood Safety
- Increasing Risk
- Epidemiology
- “The next HIV”; Known Pathogens
- High Risk Behaviors
- All Americans; All who rely on blood/plasma
- Evolving Knowledge, resulting inconsistency

Working Together

- Both gay men and those in the plasma user community have been disproportionately impacted by the HIV epidemic
- Our communities have a long history of working together on shared goals related to providing HIV support, research advocacy, treatment access, and prevention programs
- We have pledged to move forward working together to critically examine and evaluate alternative policies for MSM donor deferrals
- Mutual strong commitment to the safety of our nation's blood supply

Who bears the risk?

- The discussions within this meeting should not be simply about the donor
- If there is revision in this or other deferral policies, the resulting change in risk will be borne 100% by the end-user
- However, equally important, we are concerned about what happens in the middle; from the time an individual decides they would like to donate to the time that donation ultimately is administered or injected into our bodies
- The regulatory framework, oversight, collection and processing systems are fundamentally important

Proper Forum

The ACBSA consideration of this issue should not supplant the rigorous scientific review of the FDA and BPAC.

- The issue of MSM donors involves a mix of societal, economic and scientific issues
- This hearing provides a forum for discussing these issues
- However, the ultimate scientific decisions are and must remain within the purview of the FDA and the advice of the Blood Products Advisory Committee (BPAC)

Potential Policy Options Based On Existing Scientific Knowledge

1. Status Quo
2. Define a research agenda to be completed and analyzed prior to implementation of any policy revision
3. Recommend an immediate revision in the deferral policy coupled with an enhanced biovigilance/hemovigilance system and/or research program
4. Completely lift the deferral

Committee Questions

1. What are the most important societal, scientific and economic factors to consider in making a policy change?
2. Is the currently available scientific information including risk assessments sufficient to support a policy change at this time?
3. What studies, if any, are needed before implementing a policy change?
4. What monitoring tools or surveillance activities would need to be in place before implementing a policy change?
5. What additional safety measures, if any, are needed to assure blood safety under a revised deferral policy?

Question 1.

What are the most important societal, scientific and economic factors to consider in making a policy change?

Precautionary Principle

IOM Report Recommendation #6 states:

- “Where uncertainty or countervailing public health concerns preclude completely eliminating potential risks, the FDA should encourage, and where necessary require, the blood industry to implement partial solutions that have little risk of causing harm“
- *The report goes on to explain that, in all fields, decision-making under uncertainty requires an iterative process. As the knowledge base for a decision changes, the responsible agency should reexamine the facts and be prepared to change its decisions*

Discrimination

- We recognize and empathize with the position of those advocating for a repeal or revision of the current donor deferral policy
- By their very nature, blood donor screening and deferral criteria are discriminatory
- However, they are justifiable when they provide increased protection to public health

Epidemiology

- Epidemiology, is a science based on discrimination
- Criteria for donor deferrals must put safety of the recipient first and be based on scientific and epidemiological evidence about large groups of people (populations)
- Donor deferrals are not judgments about the individual donor
- Rather they are a method to reduce the risk of known, unknown, undetectable, or emerging viruses and/or other disease-causing agents being passed to recipients of blood or blood products

Established Evidence

- Testing and pathogen reduction technologies are not perfect, and it continues to be necessary to decline donations from some populations based on established epidemiological evidence
- CDC data indicate HIV infection rates in the U.S. are falling in heterosexuals and intravenous drug users, they are rising in MSM
- The rate of new HIV infections in MSM is 44 times the rate of new infections in other men; >50% of all new HIV infections / year are in MSM

Blood Supply

- We are eternally grateful for the altruism and generosity of those who donate. Without these lifesaving donations most in our community would not be here today
- A revision in deferral policy cannot be justified simply on the basis of the small percentage of additional donations that would be added to the national supply
- Estimates show a $\approx .5\%$ increase in the ≈ 15 million pints of blood collected annually if deferral standards were harmonized with the heterosexual population

Committee Question 2.
**Is the currently available
scientific information including
risk assessments sufficient to
support a policy change at this
time?**

Time to revise the policy?

- Currently available knowledge and data are not sufficient to support a change at this time
- We agree the scientific basis for the permanent deferral requires review
- There is not currently enough information to determine if a one-year, five-year, ten-year, or another deferral period would be more appropriate
- Selection of another interval could also be perceived as arbitrary, lacking scientific foundation or an incomplete solution as well

Time to revise the policy? (contd.)

- We believe that there are a number of factors which should be fully evaluated before making a revision to the policy
- Such evaluation and research could lead to a policy revision that maintains or enhances blood safety
- We foresee a time when a revision would be appropriate and donor deferrals should be made on a more individualized, behavioral-based risk review for both MSM and heterosexuals

Committee Question 3.
**What studies, if any, are needed
before implementing a policy
change?**

A CALL FOR ANSWERS

THE RESEARCH AGENDA

- 1. Achieving a better understanding of known and emerging pathogens in specific populations including MSM and heterosexual populations**
- 2. Developing policy that recognizes societal aspects of the blood system's safety and risk tolerance**
- 3. Developing alternate donor deferral strategies and the risk of blood-borne diseases**
- 4. Establishing a framework for accelerated approval of pathogen reduction, removal and/or inactivation technologies for fresh components**
- 5. Understanding the implications of a revision on the supply and availability of treatment products globally**

Known and Emerging Pathogens

We must achieve a better understanding of known and emerging pathogens in specific populations including MSM and heterosexual populations.

- There is a risk of new, emerging pathogens, “the next HIV”, that are not yet known, just as HIV was unknown prior to 1981 with the same transmission route as known sexually transmissible viruses
- Incubation period could be > 5 years or take even longer to fully understand transmission (e.g. HHV8, HCV, vCJD, XMRV)

68 Emerging Pathogen Threaten the Blood Supply

THE WALL STREET JOURNAL.

WSJ.com

THE INFORMED PATIENT | MAY 24, 2010

New Threats to U.S. Blood Supply

By LAURA LANDRO



Public health officials are battling a host of new infectious threats to the nation's blood supply.

Blood centers, which have long tested for risks like hepatitis C and AIDS, have added a number of new tests on donated blood in recent years, including checks for West Nile virus and Chagas, a tropical parasitic disease.

But new screening tests are hard to develop and can take years to win government approval. Currently, for instance, there's no way to screen for newer threats like babesiosis, a parasitic infection that has been linked to 10 U.S. deaths through blood transfusions since 2006. And a dangerous virus known as Chikungunya has spread to the U.S. and Europe from Africa in the last several years.

Blood supply officials are urging the U.S. government to adopt so-called pathogen-reduction technology that can kill a wide range of contaminants in blood after it has been donated. One method already in use in about a dozen countries in Europe, Asia and elsewhere destroys most pathogens with a combination of chemicals and ultraviolet light. The Food and Drug Administration declined to approve the technology several years ago, citing possible side effects. But the agency is continuing to evaluate it.

Societal Considerations

Behavior-based Questionnaire

We must give due consideration in policy development to the societal aspects of the blood system's safety and risk tolerance.

- How could we adapt the donor screening so that the altruistic interests of the donor are respected in the least prejudicial way consistent with the reality that the end-user bears 100% of the risk?
- Will the responses be truthful and complete?
- Will the answers be useful in screening out individual high risk donors?

Donor Tracking

- The potential for testing / recordkeeping errors are an important consideration when evaluating donor reentry
- The underlying system for tracking donors and quarantined donations must be implemented uniformly and performing optimally across the nation's blood systems
- It will be several years before all segments are automated
- It remains troubling the ARC has been under consent decree for 17 years
- We seek assurance the risk of quarantine release errors will not be exacerbated by this situation

Alternate Donor Deferral Strategies Pre-Test / Pre-Screening

We must consider alternate donor deferral strategies and the resulting risk of blood-borne diseases.

- It may not be appropriate to continue to consider MSM as a homogenous group
- A “pre-test” coupled with an enhanced questionnaire may establish a more complete “pre-screening” profile
- Would it then be possible to correlate high risk behavior to allow a differentiation among both MSM and Heterosexual donors for high risk behavior?

Estimating True and Total Risk

We must factor into the equation the risk of multiple and cumulative exposure for those dependent upon blood and plasma therapies for their daily living.

- The number of potentially infectious donations which might enter the blood supply is not known or agreed
- Each blood donation is typically split into three components – red cells, platelets and plasma – which could multiply the impact of an infectious donation
- We must also factor into the equation the risk of multiple and cumulative exposure for new, known, and emerging risks by chronic blood / plasma users

Pathogen Reduction

We must establish a framework for accelerated approval of pathogen reduction, removal and/or inactivation technologies for fresh components and where necessary support research to develop the technology.

- Pathogen reduction is the “Holy Grail” of blood safety
- For labile (fresh) blood components, donor selection and donor screening are the only gatekeepers
- Screening tests are only available for some pathogens
- Current testing and donor questionnaires are not enough to guarantee safety

Global Considerations

We must understand the implications of a revision on the supply and availability of treatment products globally prior to changing the deferral policy.

- *“Blood is local, plasma is global”*
- Products manufactured using MSM donations may not be suitable for global markets and could impact the global availability of plasma-derived medicinal products
- est. 2010, 32.8 million liters of plasma (recovered and source) collected worldwide; 20.4 million liters (62%) from North America; vast majority from U.S.

Committee Question 4.
What monitoring tools or surveillance activities would need to be in place before implementing a policy change?

Hemovigilance / Biovigilance

We must have a robust comprehensive hemovigilance and biovigilance program.

- Development of a robust systemic approach is critical to track and counter known and emerging infectious threats to the blood supply
- Work of the ACBSA is commendable but not complete
- Donor screening, donor deferral, and donor testing measures alone are an inadequate solution to a growing and complex problem

Committee Question 5.
What additional safety measures, if any, are needed to assure blood safety under a revised deferral policy?

Approval of Pathogen Reduction Technologies

We call upon the Department of Health and Human Services to encourage accelerated development and use of pathogen reduction technologies for fresh (labile) components

- Technologies for pathogen reduction of fresh components are developing and must be encouraged
- e.g., Preparation of virally inactivated, solvent-detergent-treated cryoprecipitate has advanced considerably

Donor Education and Marketing

We must implement a robust donor education program as part of any revised donor deferral policy.

- This has been an issue filled with misunderstanding
- Recruitment messages delivered to prospective donors and donors reentering the system must be clearly conveyed
- Changed perceptions of acceptability must be managed
- If a change in policy leads to a differentiation among high-risk behaviors it will be essential to have clarity in the donor screening questions

Summary of Research Recommendations

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- I. The ACBSA consideration of this issue should not supplant the rigorous scientific review of the FDA and BPAC.**
- II. We must achieve a better understanding of known and emerging pathogens in specific populations including MSM and heterosexual populations.**
- III. We must give due consideration in policy development to the societal aspects of the blood system's safety and risk tolerance.**
- IV. We must consider alternate donor deferral strategies a the resulting risk of blood-borne diseases.**

Summary of Research Recommendations (contd.)

- V. We must factor into the equation the risk of multiple and cumulative exposure for those dependent upon blood and plasma therapies for their daily living.**
- VI. We must establish a framework for accelerated approval of pathogen reduction, removal and/or inactivation technologies for fresh components and where necessary support research to develop the technology.**
- VII. We must understand the implications of a revision of the donor deferral policy on the supply and availability of treatment products globally prior to changing the deferral policy.**

Summary of Research Recommendations (contd.)

- VIII. We must have a robust comprehensive hemovigilance and biovigilance program.**
- IX. We call upon the Department of Health and Human Services to encourage accelerated development and use of pathogen reduction technologies for fresh (labile) components.**
- X. We must implement a robust donor education program as part of any revised donor deferral policy.**

Conclusion – A Call for Answers

- We acknowledge that the scientific basis for the permanent deferral requires review
- We believe that there are a number of factors which should be fully evaluated before making a revision to the policy
- Such evaluation and research could lead to a policy revision that **maintains or enhances the safety of blood and blood products**

We urge the ACBSA to support the necessary research and evaluation prior to adopting a policy revision.