MSM Donor Deferral

Mark W. Skinner
WFH President
Both gay men and those in the plasma user community have been disproportionately impacted by the HIV epidemic.

The two communities have a history of working together on shared goals related to providing HIV support, research advocacy, treatment access, and prevention programs.

Mutual strong commitment to the safety of the blood supply.

• “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”

• “…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.”

Source: IOM Report “HIV and the Blood Supply” Recommendation #6
Framing the Debate / Balancing the Issues

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

- Epidemiology
- Blood Safety
- Increasing Risk
- “The next HIV” / Other Pathogens
- High Risk Behaviors
- All who rely on blood / plasma
- Evolving Knowledge
By their very nature, blood donor screening and deferral criteria are discriminatory.

Epidemiology, is a science based on discrimination.

Criteria for donor deferrals must put safety of the recipient first and are based on scientific and epidemiological evidence about large groups.

Donor deferrals are not judgments about the individual donor, but rather are a method to reduce the risk from known, unknown, undetectable, or emerging pathogens.
Societal Considerations – Behavioral Questions

• Is it appropriate to continue to consider MSM as a homogenous group?

• Is it possible to correlate high risk behavior to allow a differentiation among both MSM and heterosexual donors for high risk behavior?

• Will the responses be truthful and complete?

• Will the answers be useful in screening out individual high risk donors?
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 that while 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.
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.
Quarantine Release Errors (QREs)

- Information known PRIOR to distribution of product that warrants quarantine; product subsequently distributed
- The potential for testing or recordkeeping errors are an important consideration when evaluating newly eligible donors
- “QRE’s remain the most significant preventable source of risk.”
There must be 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
- Donor screening, donor deferral, and donor testing measures alone are an inadequate solution to a growing and complex problem
• 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
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.
Study Overview and Timeline

- **TTD risk in current donors**
  - 18-24 months

- **Root Cause Analysis of Quarantine Release Errors**
  - Donor Evaluation
    - Interpretation and understanding of questions
    - Motivation of donors

- **Screen Strategy**
  - Pilot study with interim policy of shortened MSM deferral activity

- **Review of MSM Deferral Policy**
  - 24-36 months
  - Pending available funding
1. How does the risk of blood transmissible diseases in the current donor population relate to risk factors in donors?

Source: U.S. HHS Plan of Action for the re-evaluation of the MSM deferral policy – 22 July 2011
2. What is the root cause of Quarantine Release Errors (QRE) that is accidental release of blood not cleared for use that occur at blood collection centers and potentially put the blood supply at risk and what mitigations can be considered?

Source: U.S. HHS Plan of Action for the re-evaluation of the MSM deferral policy – 22 July 2011
3. Donor evaluation:

- Do potential blood donors correctly understand and properly interpret the current standard questionnaire used to obtain donor history?

- What motivates a man with MSM behavioral history to donate and would MSM be likely to comply with modified deferral criteria?

Source: U.S. HHS Plan of Action for the re-evaluation of the MSM deferral policy – 22 July 2011
4. Would alternative screening strategy (e.g. pre- and/or post qualifying pre-donation infectious disease testing) for MSM (and potentially other high-risk donors) assure blood safety while enabling collection of data that could demonstrate safe blood collection from a subset of MSM or other currently deferred donors (e.g. men with a history of abstinence from MSM behavior for a defined time period)?

Source: U.S. HHS Plan of Action for the re-evaluation of the MSM deferral policy – 22 July 2011