

Health and Human Services (HHS) Activities and Response to Men who have had Sex with other
Men (MSM) Blood Donor Deferral Policy Questions
July 22, 2011

1. What actions is the Secretary of HHS is taking with regard to the MSM blood donor policy deferral?

After the July 2010 [Recommendations from the Advisory Committee on Blood Safety and Availability \(ACBSA\)](#) regarding lifetime deferral from blood donation of MSM, HHS undertook significant internal action to examine the policy. We weighed the Committee's view that the current deferral as suboptimal and the Department's primary concern regarding the safety of the blood supply and protecting the public. To address these concerns, Dr. Howard K. Koh, Assistant Secretary for Health, charged the Blood, Organ, and Tissue Safety Working Group (BOTS WG) to develop a plan of action based on the ACBSA June 2010 recommendations, including conducting the necessary studies to allow a further review of the existing policy. The BOTS WG is composed of representatives from the Public Health Service (PHS) Agencies as well as the Centers for Medicare and Medicaid Services (CMS). The BOTS WG has been meeting on a regular basis over the last year.

The BOTS WG determined that additional studies are needed in order to yield the appropriate data necessary for the re-evaluation of the current deferral policy.

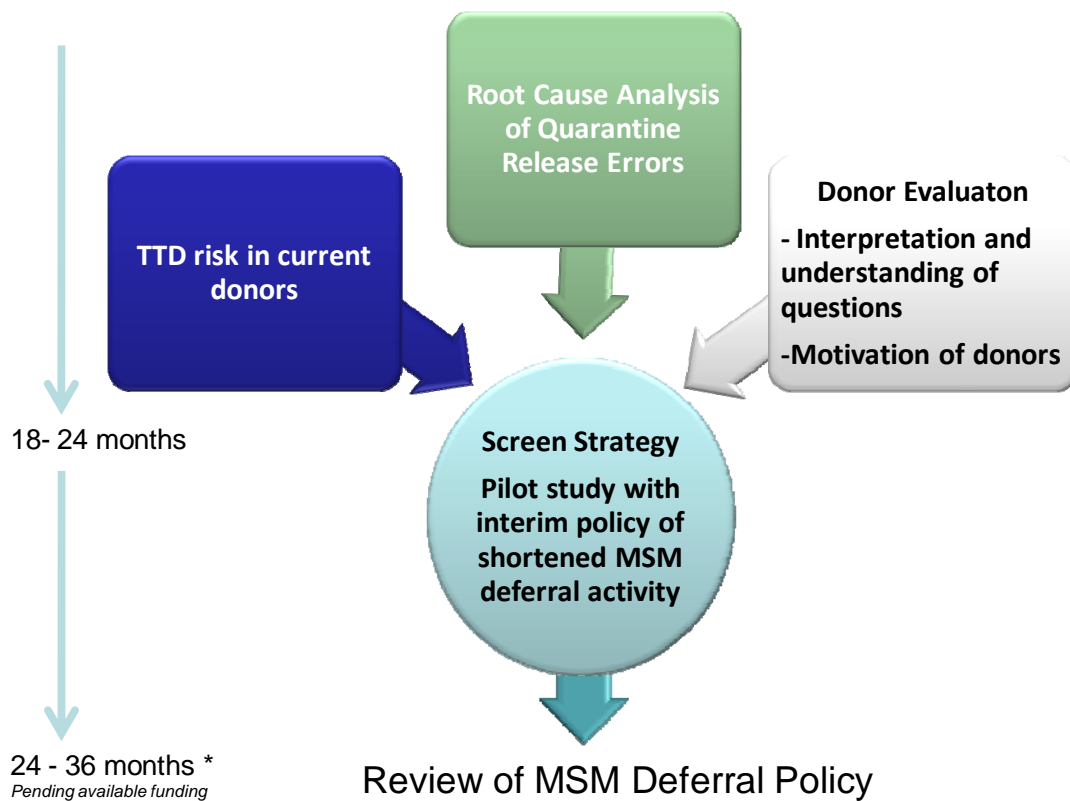
2. What additional studies or other information are needed to implement a policy change?

The BOTS WG proposed studies aim to address the questions which need data to answer, including:

- a) How does the risk of blood transmissible diseases in the current donor population relate to risk factors in donors?
- b) What is the root cause of Quarantine Release Errors (QRE), the 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?
- c) Donor evaluation:
 - 1) Do potential blood donors correctly understand and properly interpret the current standard questionnaire used to obtain donor history?

- 2) What motivates a man with MSM behavioral history to donate and would MSM be likely to comply with modified deferral criteria?
- d) Would alternative screening strategy (e.g. pre- and/or post qualifying 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)?

The design and implementation of necessary studies to answer these questions are dependent on funding which affects the timeline for data collection and the timeline for a potential policy revision.



3. What has HHS done to this point in time?

Although funding is limited, the Department and its Agencies recognize the need to build on the current momentum to improve the existing policy raised internally as well as by the constituencies of patients who frequently use blood products (e.g., people with bleeding disorder), potential donor communities (e.g. gay and bisexual men), and advocacy groups. The following efforts are underway and are organized according to the identified research questions listed in question 2:

- a) To answer the first question stated above, a study of baseline data on risk of blood transmissible diseases in relation to behavioral risk factors in current donors was initiated in 2011. Funding to support this is from the National Institutes of Health (NIH), National Heart, Lung and Blood Institute's (NHLBI) Retrovirus Epidemiology Donor Study-II (REDS-II link).
- b) The second research question stated above addresses a system issue related to errors that occur due to accidental release of units that have not met all criteria necessary for release. Although these errors are rare, they represent a potential weakness in the current system. To identify and understand the potential causes for these errors, FDA will hold a public workshop with blood establishments and other stakeholders in September 2011.
- c) Evaluation of the donor history is in two parts:
 - 1) The first is the understanding and interpretation of the donor history questionnaire. Although a plan has been identified through CDC to evaluate the donor cognitive or understanding of the current history questionnaire, this is currently unfunded.
 - 2) Separately, a study of attitudes and motivations among men with MSM behavior history with a history of donation or might donate under revised deferral criteria has been partially funded by FDA. Ways to further support and also expand the study are under discussion.
- d) The design of a donor screening strategy to permit donation by some men with history of MSM behavior while assuring blood safety and gathering information necessary to support donation by a safe subset of MSM (or other currently deferred persons) is under review. In particular, the BOTS WG is exploring the design of a pilot project with pre- and post-donation screenings for deferred donors.

The Department's Blood, Organ, Tissue Senior Executive Council is currently assessing how the above mentioned studies can be supported with limited resources to include long term monitoring through a national hemovigilance program (monitoring or surveillance of the blood supply and blood recipients).

4. Can hemovigilance or the monitoring (surveillance) of the blood supply and the recipients of blood products play a role in this process? If so, how?

As a long term strategy, the BOTS WG recommended that surveillance be established through a national hemovigilance program (e.g., blood donor and blood recipient surveillance) to monitor safety impacts of any change in policy. Both public health surveillance and regulatory reporting are critical to monitor current policies, as well as changes in policies, to ensure a continuous improvement process.

5. What might a new policy look like? What additional safety measures might be included if the MSM policy is changed?

The Department is committed to continuous improvement in the nation's blood supply taking into account new and emerging scientific information. It is anticipated that the described studies will yield data for re-evaluation of the current deferral policy and potentially establish safety of 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).

6. Under what circumstances would HHS bring this issue before an advisory committee again?

When the results and data from the studies are available and potential policy revisions are brought forward for consideration, there will be opportunities for discussion in a public forum. The decision to bring this back to either the Secretary's Advisory Committee on Blood Safety and Availability or the FDA's Blood Products Advisory Committee for further review is dependent on the specific questions on which the Department may seek advice or recommendations.

7. Do you foresee a change in the MSM policy? Why or why not?

The Department has worked to develop a plan that will yield scientific data that are currently needed to re-evaluate the current policy based on the ACBSA recommendations. When these studies are complete, the Department is committed to a full evidence-based evaluation of the policy. If the data indicate that a change is possible while protecting the blood supply, we will consider a change to the policy.