



#### **Defense Health Board**











#### DEFENSE HEALTH BOARD

## Question to the Board

DoD Policy on Emergency Blood Transfusions in Combat Theaters and Impact on HIV Testing Policy



 OIF and OEF combat operations have resulted in instances of blood collection under emergency protocol and transfusion without complete FDA-approved testing.

#### The Board was asked to:

- Review the issues associated with collection and transfusion of blood products under emergency conditions in a combat environment
- Provide comments and recommendations regarding optimal strategies to minimize risk.

### Background

- Majority of transfusions employ FDA-licensed blood products received in theater through a single Blood Transshipment Center.
  - The Center is control point for providing blood and blood products to medical treatment facilities of all levels within the AOR.
  - Twice-weekly scheduled shipments of over 1,000 units to medical facilities throughout the AOR
  - Meet routine needs.
- In excess of 5,000 instances of emergency blood transfusions
  - Limited blood screening under emergency protocol
    - HIV using rapid testing Not an FDA-approved test for blood donation
    - Donors are "Prescreened" in some cases
      - Samples sent to US for testing before blood products are given,



#### Background

- Service members submit serum specimen before deploying (Public Law and DoD Requirement)
  - No testing required, but majority of specimens are HIV tested
  - Sample collected within 1 year of deployment
- Members are routinely tested for HIV every 2 years
- No routine test for HCV
- HBV screening and immunization of new military accessions by DoD policy



- Two scenarios where emergency transfusions occur
  - Mass casualty events
    - Local blood and blood product supply is exhausted
  - Massive severe trauma
    - Patients requiring large number of transfusions
    - Provider preference of fresh whole blood and platelets
      - Limited field evidence of enhanced survival



#### Dilemma

- DoD must provide a safe blood supply
  - Combat operations/mass casualties create situations where "safe" is not attainable
  - While blood transfusion risks can be reduced, does not = "safe"
- DoD must provide the best trauma care available
  - Combat poses unique trauma challenges
  - Historical precedence for advances in trauma care from combat
  - Data collection in combat is difficult or impossible
  - Valid evidence of benefit is required before subjecting patients to untested blood products' risks

# Recommendations The Department should engage in these <a href="mailto:concurrently">concurrently</a>

- Limit emergency blood transfusion protocols to instances, such as mass casualty events, where the available supply of FDA-licensed blood and blood products are exhausted.
- Pre-deployment HCV testing to reduce the risk of blood transfusion-related infections.
  - Can reduce the HCV risk in emergency transfusion cases
  - Carefully consider the second and third order implications of such policy
    - Impact of Reserve Component retention
    - Impact of new accession (existed prior to service)



# Recommendations The Department should engage in these concurrently

- Review the current AOR blood supply logistic system. A more agile system is required, able to meet mass casualty event needs.
- Further investigate establishing blood collection and processing capability forward in theater.
- Review the current HIV interval and pre-deployment testing policy
  - AFEB recommendations of every two years based on an assumption of rare use of a walking blood bank.
  - Assumption is no longer valid
  - Board recommends HIV interval testing every two years
  - Pre-deployment HIV testing yearly

# Recommendations The Department should engage in these concurrently

- Repeat the DoD HCV Sero-incidence Study
  - (*Am J of Epidemiol* 2001) showing sero-prevalence.
- Partner with industry to develop new FDA-licensed rapid testing methods for blood collection
  - HIV rapid test with acceptable sensitivity and specificity but not FDA approved for blood collection
  - Effective rapid HCV/HBV tests needed
    - Issue of national interest during domestic mass casualty events
- Ensure a comprehensive "Look Back" program



# Recommendations The Department should engage in these concurrently

- The use of untested fresh whole blood and blood products outside of established, human subjects protected trauma protocols should be discontinued.
  - Novel trauma treatment approaches should be conducted under protocol, even in a combat environment.
  - Joint Theater Trauma Team should lead the effort to improve data collection and evidence for novel trauma methods, particularly relating to the use of fresh whole blood and platelets.