Defense Health Board

Question to the Board

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

Emergency Blood Transfusions

- 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.

Emergency Blood Transfusions

- Background
  - Majority of transfusions employ FDA-licensed blood products received in theater through a single Blood Trans-shipment 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

Emergency Blood Transfusions

- 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

Emergency Blood Transfusions

- 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

Emergency Blood Transfusions

- 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

Emergency Blood Transfusions

Recommendations

The Department should engage in these <u>concurrently</u>

- 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)

Emergency Blood Transfusions

Recommendations

The Department should engage in these <u>concurrently</u>

- 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.
  - <u>Assumption is no longer valid</u>
  - Board recommends HIV interval testing every two years
  - Pre-deployment HIV testing yearly

Emergency Blood Transfusions

Recommendations

The Department should engage in these <u>concurrently</u>

- 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

Emergency Blood Transfusions

Recommendations

The Department should engage in these <u>concurrently</u>

- 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.