National Blood Reserve

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AABB Interorganizational Task Force

on

Domestic Disasters and Acts of Terrorism

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Task Force Mission

- During times of disaster:
 - Coordinate blood inventory management in U.S.
 - Manage donor response and collections in excess of actual need

Requested by Blood Safety and Availability Committee to:

 Develop a plan for establishing a National Blood Reserve for disaster response

Task Force Participants

- Level 1
 - AABB, ABC, ARC, BCA, ASBPO, FDA, CDC, HHS
- Level 2
 - AATB, AHA, PPTA, AdvaMed,
 FDA-Communications, CAP
- Blood Reserve Work Group
 - AABB, ABC, ARC, BCA, DoD

National Blood Reserve Purpose

- Respond to Civilian Need: Health Emergency, Disaster or Act of Terrorism
 - Supply Disruption related to Donor Ineligibility and/or Product Quarantine
 - Increased Demand relating to Casualty Treatment
- Respond to Military Need:
 - Initial Shipments for No or Short-Notice Conflicts
 - Reduce Reliance on Frozen Reserve

Task Force Considerations

Incorporated Lessons Learned from Real Disasters and National Exercises

- Embassy Bombings in Africa, Oklahoma, 9/11
- Local Disasters Floods, Hurricanes, Tornadoes
- TOPOFF 2 Exercise
- Military Operations

Task Force Considerations

Examined Existing Models for Comparable National Reserve Operations

- The Strategic National Stockpile (Pharmaceuticals)
- DoD War Reserve Materiels
- Vendor Managed Inventory
- Corporate Exigency Contracts
- Civil Reserve Air Fleet (CRAF)
- National Disaster Medical System (NDMS)
- The Strategic Oil Reserves
- Other DoD Systems Readiness Mgt. Application(RMA);
 Industrial Preparedness Planning (IPP)
- Industrial Base Capacity

Task Force Recommended Reserve Characteristics

- > Liquid RBCs As, Bs, and Os
- > Approximately 10,000 units
- **➤** Designated Storage Sites
- > Available for Shipment in 4-6 Hours
- > Rotation of Reserve Every 2 Weeks
- ➤ Combination of Government & Private Sector Control over 10,000 units

Why Liquid not Frozen?

 Burden of maintaining/updating the frozen units to meet current FDA/AABB testing and donor screening requirements

- Logistical drawbacks
 - Slow process (1 unit/machine/hour)
 - 14 days post-thaw shelf-life
 - Ultra low storage temperature requirements

Why Liquid not Frozen?

Stock Rotations

- Costs (\$28.7 M)
 - \$5 M investment + rotation (\$500 per unit)
 - \$23.7 M equipment (500 machines + 20 freezers)

Why Just Liquid RBCs?

- Platelets
 - 5 day shelf-life not practical
- Plasma and other components could be added

10,000 Units

Based on:

- Blood Product Loss in TOPOFF 2 Exercise
- Loss of Total Blood Supply in 2 Major Metropolitan Areas
- Need to Immediately Provide a 3 Day Replacement Supply

Designated Storage Sites/Shipment in 4-6 Hours

- Designated Storage Sites Provide
 - Nationwide Coverage within 4 to 6 hours
- Not Virtual or Frozen
 - Available immediately when needed
- Satisfies Military Need for No or Short-Notice Shipments

Rotation of Reserve Every 2 Weeks

- Shelf Life of 42 days
- 3 Days Required for Processing
- Hold for 2 weeks prior to distribution
- Reserve units will be 2.5-3 weeks old when distributed

Combination of Government/Private Sector Control

- 2000 units controlled by government, held by government through DoD
- 8000 units controlled by government, coordinated by the Interorganizational Task Force, held in Regional Blood Centers

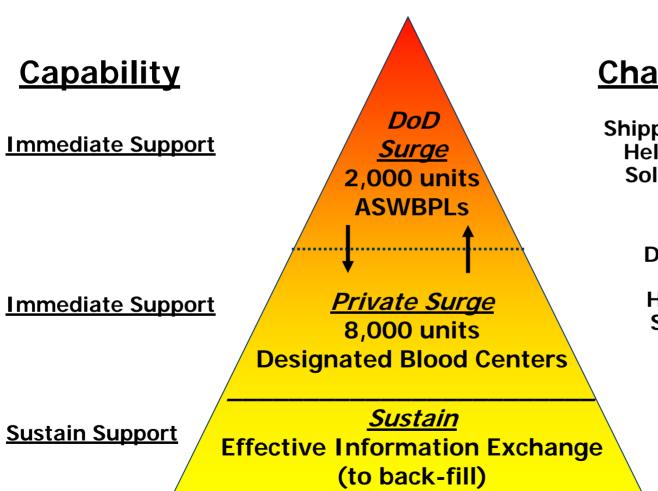
Why Government/Private Sector Control?

- Need is public: Federal, state, or local emergency plan and response
- Source is private: The individual donor, supplied through regional blood centers
- Government investment is required: Federal funding through contracts or grants to DoD and Regional Blood Centers is necessary to establish and maintain a National Blood Reserve

Existing Examples for ReserveManagement Options

	Option 1	Option 2	Option 3
OWNERSHIP	FEDERAL	FEDERAL	PRIVATE
		(by contract)	
CONTROL	FEDERAL	FEDERAL	PRIVATE
STORAGE	FEDERAL	PRIVATE	PRIVATE
VISIBILITY/	FEDERAL	PRIVATE	PRIVATE
INFORMATION		(report to Federal)	
EXAMPLES	HHS/SNS	HHS/SNS	Industry
	(Pharma (VMI)	(VMI)	Coordination
	Push		(Interorgani-
	Packages)		zational Task
			Force)

National Blood Reserve: A Single Program With Levels of Response



Characteristics

Shipped to ASWBPLs Held for 2 Weeks Sold to Hospitals

Collected by
Designated Blood
Centers
Held for 2 Weeks
Sold to Regional
Blood Centers

Information
Exchange through
Task Force
Goal: Maintain 5-7
day supply RBCs

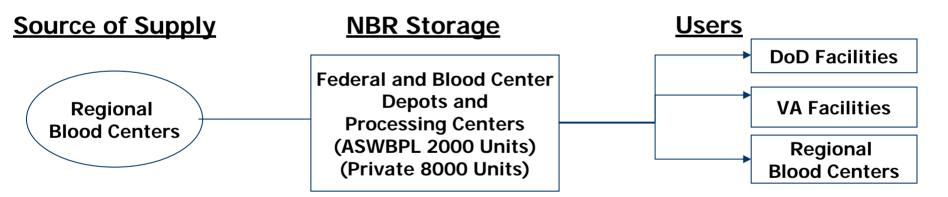
NBR Recommendation

Characteristics

- Federal/Private Partnership
- Real Units on the Shelves
- Secure
- Access to Distribution

Operations

- Federal Depots and Designated Regional Blood Centers under contract with Government
- Blood rotates through Depots/Centers to be available as a reserve
- After 2 weeks, distributed through contracts with healthcare facilities and Regional Blood Centers



<u>Transportation and Distribution through Use of Existing Contracts</u>

<u>Such as Those Used to Move the SNS</u>

National Blood Reserve What Is It?

- Capability to Ship Blood within 4-6 Hours
- Program, Structure, Management, Coordination
- Contingency Planning / Crisis Response
- Information
- Supporting Capabilities (e.g. supplies)
- Transportation and Distribution
- Public/Private Control
- What is it Missing? \$\$\$\$\$

Cost Considerations

2,000 Units @ ASWBPL	Start Up Costs	Annual Cost
Initial purchase @ \$225/unit - establish reserve	\$450,000	
Capital investment for refrigeration and facility space to store reserve		\$0.00
Operational costs to rotate reserve (shipment)		\$ 520,000
Reimbursement for discounted value to rotate units (10% value per unit lost due to shorter shelf life after		
processed through reserve)		\$1,040,000
Total Costs	\$450,000	\$1,560,000

Cost Considerations

8,000 Units @ REGIONAL BLOOD CENTERS	Start Up Costs	Annual Cost
Initial purchase @ \$225/unit - establish reserve	\$1,800,000	
Capital investment for refrigeration and facility space to store reserve	\$340,000	
Operational costs		\$1,040,000
Reimbursement for discounted value to rotate units (10% value per unit lost due to shorter shelf life after processed through reserve)		\$4,160,000
Total Costs	\$2,140,000	\$5,200,000

More Cost Considerations

- Additional costs:
 - Increased cost of blood due to inflation and new safety measures
- Discounted value must be tested in market conditions
- Implementation strategy: A phased-in approach lessens full investment requirement in early stages

Total Anticipated Costs

Start Up Costs

\$ 2,590,000

Annual Costs

\$6,760,000

Critical Success Factors

- Key to Success of any Blood Reserve is a Stable and Adequate Blood Supply
 - Requires Federal Support of National Awareness Campaigns
 - At levels Comparable to HHS Organ and Tissue Donation Campaigns

Implementation

- Government Approves Concept and Funds Program
- Use Existing Resources to fill 2,000 Unit Reserve
- National Awareness Campaign Developed
- Government and Private Sector Develop Contracts to fill 8,000 unit reserve
- Task Force and Government Develop Policies for Authorizing Use of the NBR
- Information Processes and Tools Established to Manage NBR

Benefits of National Blood Reserve

- Draws on Existing Public and Private Infrastructures and Systems
- Forces Commitment to Public Campaign to Increase Donors
- Modest Cost
- Supports Critical Infrastructure Imperatives of Homeland Security

Recommendation

That the Advisory Committee on Blood Safety and Availability:

- 1. endorse the concept of a National Blood Reserve Program with the characteristics recommended by the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism; and
- 2. recommend that the Assistant Secretary for Health further develop, in cooperation with the private sector, details of such a plan, and secure federal funding for this program.

Management Structure

