



Armed Services Blood Program

DOD's Policy on Theater Emergency Blood
Collections and Transfusion

Impact on HIV and Hepatitis Policy

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Armed Services Blood Program



Question to the Board:

Request that the Board review issues associated with the practice by physicians to collect blood products in the field and transfuse under emergency conditions in a combat environment and provide recommendations regarding optimal strategies to minimize risk.

In particular, the Board should consider issues related to the risk for Human Immunodeficiency Virus (HIV) and hepatitis infections from blood products collected and transfused in the field.



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- To date, approximately 5,500 blood products have been collected and transfused under “emergency protocol” in OIF and OEF.
- The practice of collecting and transfusing “fresh” whole blood and apheresis platelets will continue to support aggressive hemostatic resuscitation techniques performed in parallel with aggressive surgical control of bleeding.



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- The collections and transfusion of “fresh” whole blood are occurring primarily at Level II and III facilities.
- Apheresis, Platelets are collected only at 332 EMEDS Balad and 10th CSH Baghdad.

The Army Blood Support Detachment (08489A000) has emergency blood and apheresis, platelet collection capability.

Blood Transfusions by Product and Nationality of Recipient

OEF/OIF Combined

As of 31 July 2006

	Total	U.S. Only	Non-U.S.	Percent U.S. Only	Percent Non-U.S.
Transfused Patients	9,942	2,848*	7,094	28.6%	71.4%
WB	3,393	2,095	1,298	61.7%	38.3%
RBCs	56,817	16,563	40,254	29.2%	70.8%
Platelets	1,892	695	1,197	36.7%	63.3%
FFP	22,811	7,398	15,413	32.4%	67.6%
Cryo	6,928	3,009	3,919	43.4%	56.6%

* Only 14.1% of total U.S. Wounded In Action required blood transfusions.

WIA = 20,170 (OEF/OIF combined)

(Source: WHS)

5,285 total emergency transfusions Jul 06

Blood Product Transfusions For OIF and OEF

As of 31 July 2006

		Total # Units Transfused	Total # Pts Transfused	Average # Units/Pt	Low	High
WB	OIF/OEF	3,393	641	5.3	1	36
RBCs	OIF/OEF	56,817	9,439	6.0	1	143
Platelets	OIF/OEF	1,892	701	2.7	1	29
FFP	OIF/OEF	22,811	3,461	6.6	1	98
Cryo	OIF/OEF	6,928	570	12.2	1	114



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Blood Donation Process: steps to protect the recipient.

- Identifying elements of medical history and behavior that put a donor at risk for transmissible diseases.
- Infectious Disease Testing



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Donor medical history screening questions

- Issues that impact response accuracy
 - Sensitive/stigmatizing (branding) behaviors
 - Motivation/emotion
 - Pressure
 - Time frame/memory problems
 - Donor knowledge & understanding of risk
 - Competency of blood collection personnel



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Infectious Disease Testing

The FDA requires infectious disease testing for the following:

- EIA(ELISA): HBsAg, anti-HBC, anti-HCV, anti-HTLV I/II, and anti-HIV1/2*
- NAT (Nucleic Acid Test): HIV 1, HCV, WNV*
- Syphilis*



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- Post-donation test samples sent to:
 - Wilford Hall Medical Center: EIA and NAT
 - FT Hood Blood Center: EIA only
- *BioKit* Screening Rapid Test (Spain): Not FDA licensed for HIV1/2, HCV, and HBSAG
 - *Used at 332nd EMEDS and 10th CSH.*
 - *Recommended for use throughout CENTCOM AOR*
 - *FRSS using Orasure OraQuick Advance rapid HIV 1/2.*

Not compatible with the FDA's *current good manufacturing practices (cGMP)*



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Commercially available rapid testing systems have not been submitted to the FDA for donor screening. There are assays sold for laboratory research or clinical applications.

Office of Naval Research (ONR) is sponsoring an ongoing market survey and based on preliminary data, a Broad Agency Announcement is moving through the approval process at this time. Based on the timeframe that was needed to accommodate posting the BAA, it might be a year before any funds can be applied.



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Rapid Screening Assay using BioKit

10th CSH – Nov 05 to Jul 06

332 EMED – Jul 05 to Jul 06

Tests	Total Tests per Marker	Total Pos screened (percent)	Total Pos and F/U Pos (percent)	Total Neg and F/U Neg	Total Neg and F/U Pos
HIV 1/2	1,480	2 (0.11%)	0	1,451	0
HCV	1,841	2 (0.11%)	1 (0.04)	1,450	1
RPR	1,685	1 (0.06%)	0	1,451	0
HBsAG	1,292	11 (0.85%)	11(0.85%)	1,450	1

5,285 Blood Products Transfused under the Emergency Products



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OIF/OEF up until JUL 2006 using BioKit rapid screening test

Tests	Total Tests per Marker	Total not Tested
HIV 1/2	1,480	3,805
HCV	1,841	3,444
RPR	1,685	3,600
HBsAG	1,292	3,993

**5,285 Blood Products Transfused under the Emergency Products
In OIF/OEF up to LIII**



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Retrospective testing of donor samples from Army and Navy MTFs in OIF/OEF at FT Hood Blood Center us FDA lic tests

Assay	HBsAg	HIV-1/2	HCV	HTLV-I/II
Repeat Reactive (unconfirmed)	6	8	21	15
Repeat Reactive Rate	0.13%	0.17%	0.46%	0.33%
Confirmed Positive	1	0	5	3
Positive Incidence	0.02%	0.02%	0.11%	0.07%

- **Army is not performing NAT on retro OIF/OEF samples**
- **From OEF/OIF 2003 to 01 Sept 2006, 4,598 Donations Tested at FT Hood**



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Comparison between donor populations in OIF/OEF and CONUS using EIA testing at FT Hood Army Test Center

Assay	HIV-1/2	HIV-1/2	HCV	HCV
	CONUS Donor (41,297)*	OIF/OEF Donor (4,598)**	CONUS Donor (41,297)*	OIF/OEF Donor (4,598)**
Repeat Reactive (unconfirmed)	87	8	106	21
Repeat Reactive Rate	0.21%	0.17%	0.26%	0.46%
Confirmed Positive	0	0	24	5
Positive Incidence	0.00%	0.00%	0.06%	0.11%

* 2/15/05 to 11/1/05 Historical Comparison CONUS Donor

** 2003 to 01 Sep 06



Armed Services Blood Program



Comparison between donor populations in OIF/OEF and CONUS using EIA testing at FT Hood Army Test Center

Assay	HBsAg	HBsAg	HTLV I/II	HTLV I/II
	CONUS Donor (41,297)*	OIF/OEF Donor (4,598)**	CONUS Donor (41,297)*	OIF/OEF Donor (4,598)**
Repeat Reactive (unconfirmed)	46	6	80	15
Repeat Reactive Rate	0.11%	0.13%	0.19%	0.33%
Confirmed Positive	26	1	25	3
Positive Incidence	0.06%	0.02%	0.06%	0.07%

* 2/15/05 to 11/1/05 Historical Comparison CONUS Donor

** 2003 to 01 Sep 06



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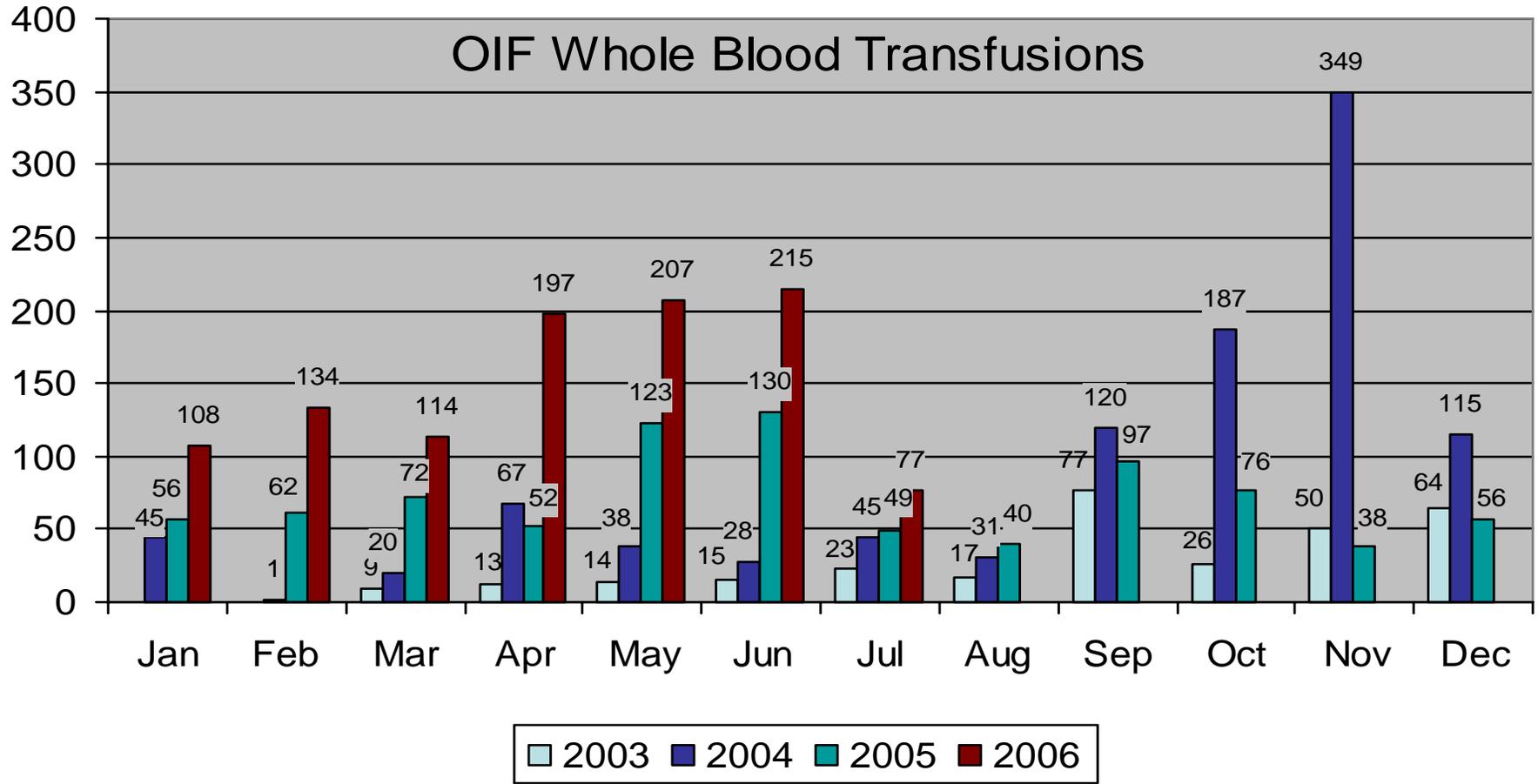
Retrospective testing of donor samples from 332 EMEDS Balad at Wilford Hall Medical Center

Assay	HBsAg	HIV-1/2	HCV	HTLV-I/II	NAT (HIV1/HCV)
Repeat Reactive (unconfirmed)	2	1	0	1	0
Repeat Reactive Rate	0.43%	0.21%	0.0%	0.21%	0.0%
Confirmed Positive	1	Results Pending	0	0	0
Positive Incidence	0.21%	0.00%	0.0%	0.0%	0.0%

•Lackland AFB performed retrospective testing on 466 donors for whole blood and platelets.

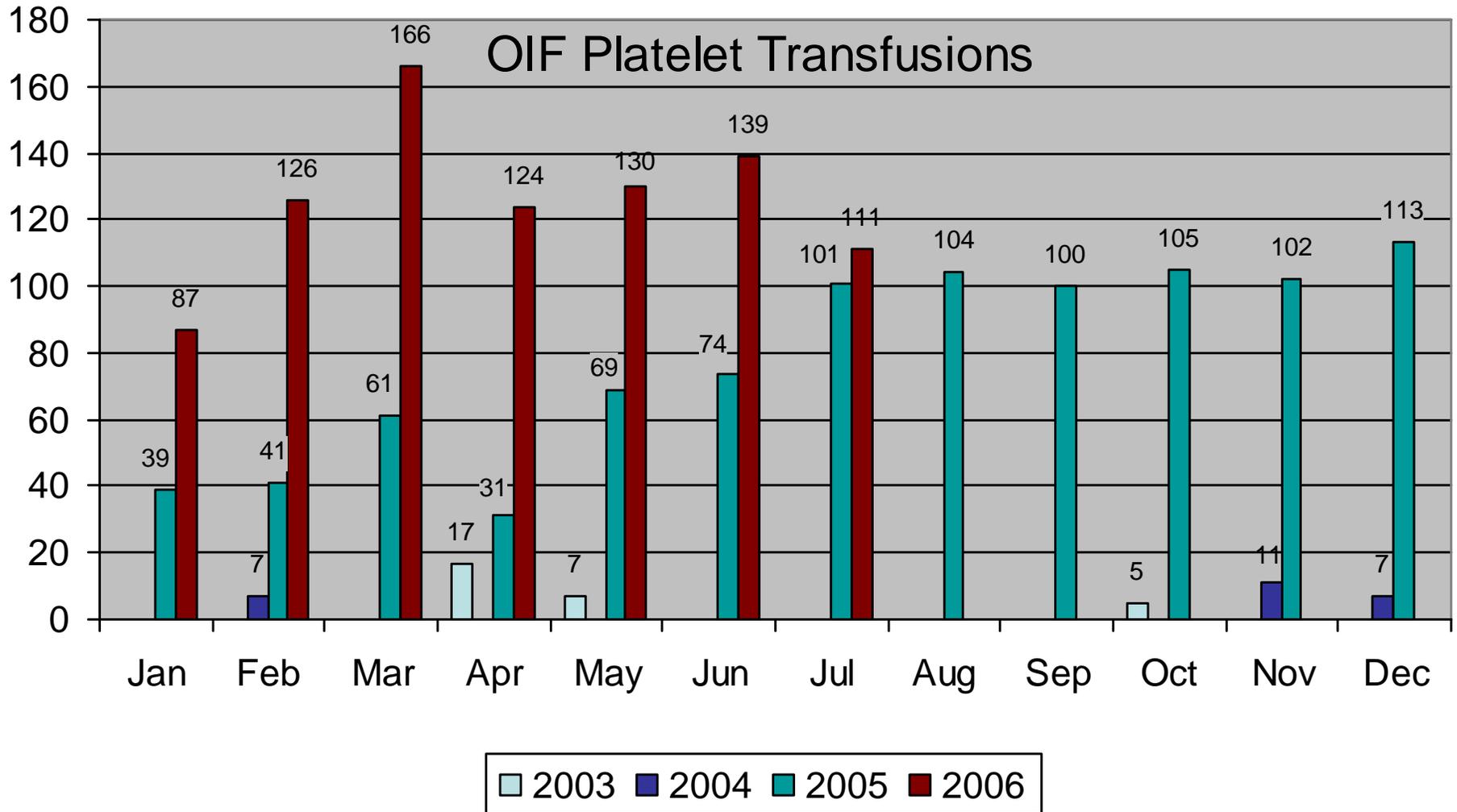
Non-FDA Tested OIF Transfused Blood Products

As of 31 July 2006



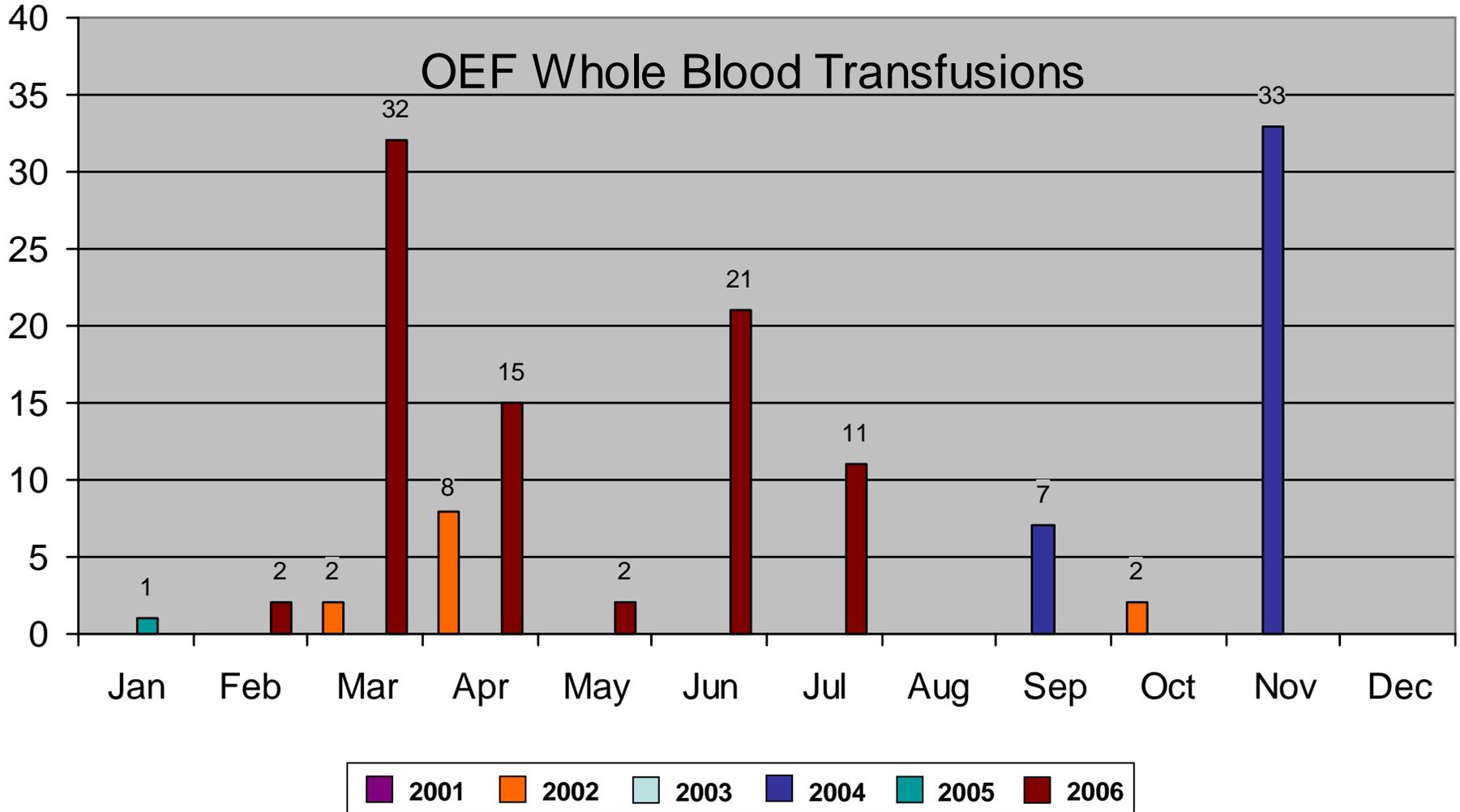
Non-FDA Tested OIF Transfused Blood Products

As of 31 July 2006



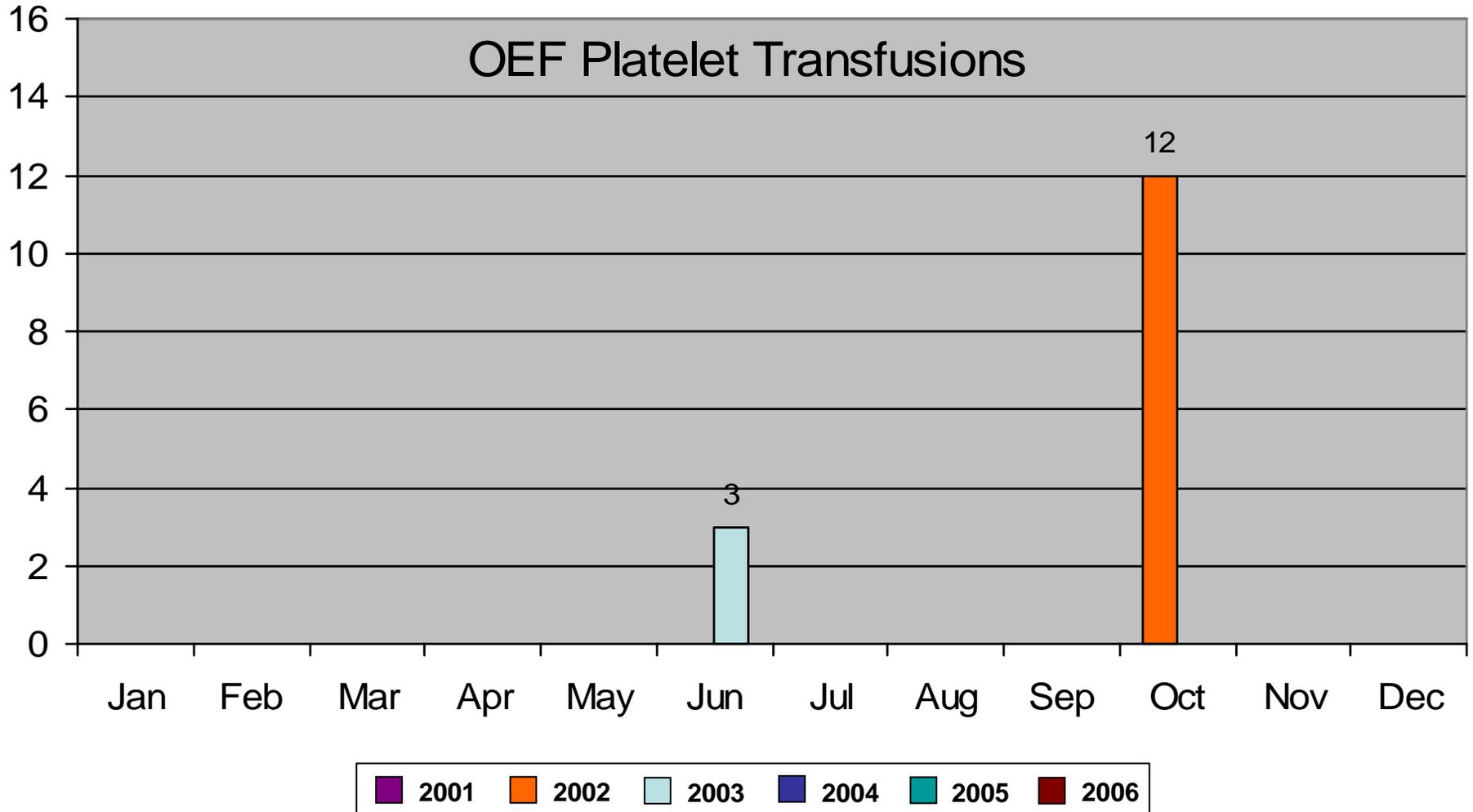
Non-FDA Tested OIF Transfused Blood Products

As of 31 July 2006



Non-FDA Tested OEF Transfused Blood Products

As of 31 May 2006





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Post-transfusion recipient follow-up

- US Active Duty
- DOD Civil Service
- US Gov't Civil Service
- Federal Contractor
- Coalition Forces
- Host nation civilians



Armed Services Blood Program



- **Information Management Systems (patient tracking)**

- Theater Defense Blood Standard System
- Joint Patient Tracking Application
- AHLTA
- Excel Spreadsheet (Mother Of All Spreadsheets) MOAS

* Management of manual or automated databases for transfusion and donation records throughout the theater medical system includes test results and post donation information needed for donor deferral and recipient look-back.



Armed Services Blood Program



Emergency WB/platelets is transfused in theater under existing Health Affairs policy (01-020 dtd 04DEC01) for use of non-FDA licensed products.

- Post-transfusion infectious disease follow-up of patient is required:
 - Pre-transfusion if possible
 - 3 months
 - 6 months
 - 12 months



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Discussion

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