

A National Biovigilance Network

Report to ACBSA

31 August 2006

**Barbee I. Whitaker, PhD
Director, Data and Special Programs**



Advancing Transfusion and
Cellular Therapies Worldwide

www.aabb.org

Biovigilance

The detection, gathering and analysis of information regarding the untoward and unexpected events of blood transfusion and transplantation of cells, tissues and organs.

with the objectives of:

- early warning of safety issues**
- exchange of valid information**
- application of evidence for practice improvement**
- promotion of educational activities**



→ safer and more efficacious transfusion

Components of Comprehensive Biovigilance

- Adverse Transfusion Events
- Infectious Disease Monitoring
- Emerging Infectious Diseases
- Hazards of Donation



Hemovigilance Networks

Partial Listing

Austria

Brazil

Czech Republic

Denmark

Finland

France

Germany

Greece

Ireland

Italy

Japan

New Zealand

Norway

Poland

Québec

Russia

Slovak Republic

South Africa

Spain

Switzerland

The Netherlands

United Kingdom



What can be learned?

Denmark

Overview of 124 Severe Risk Reports

- 6 years of data; 450,000 components transfused
- 54% IBCT
- 9% Transfusion transmitted infection
- 23% Acute reactions
 - 5% acute hemolytic
 - 10% anaphylactic
 - 9% TRALI
- 17% Delayed reactions
 - 15% delayed hemolytic
 - 1% PTP
 - 1% TA-GvH



What Can Be Learned?

Data from Poland

Table 19 Transfusion adverse reactions in recipients registered in 2003

Adverse reaction	Blood component transfused		
	Red cell concentrate	Platelet concentrate	FFP
Haemolytic reaction caused by ABO incompatibility	4	1	0 ^a
Haemolytic reaction caused by other antibodies	16	0	0
Bacterial infection	5	3	0
TRALI	3	0	0
Allergy/anaphylaxis	143	46	47
Febrile non-haemolytic	448	53	16
Others (cardiovascular, respiratory, vasovagal)	160	6	4

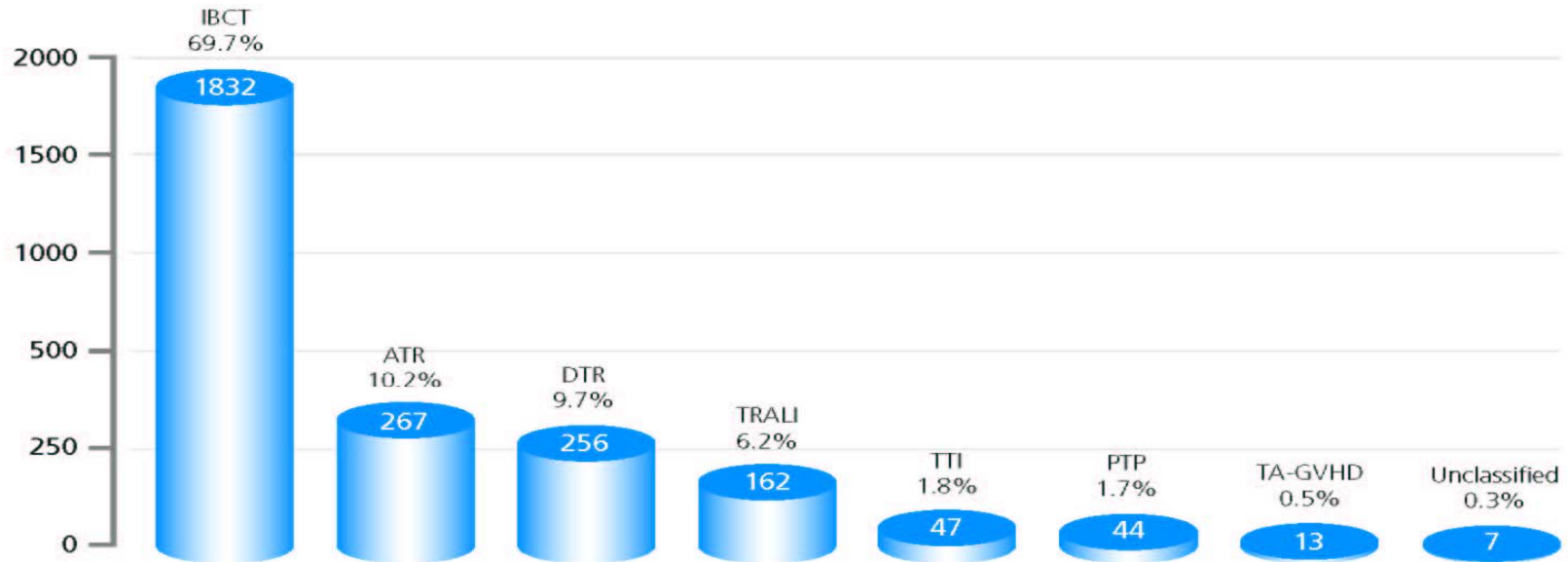
Table 22 Transfusion adverse reactions in recipients registered in 2004

Adverse reaction	Blood component transfused		
	Red cell concentrate	Platelet concentrate	FFP
Haemolytic reaction caused by ABO incompatibility	7	0	0 ^a
Haemolytic reaction caused by other antibodies	10	0	0
Bacterial infection	13	0	0
TRALI ^b	14	0	1
Allergy/anaphylaxis	97	34	28
Febrile non-haemolytic	390	36	5
Others (cardiovascular, respiratory, vasovagal)	174	38	33

What Can Be Learned?

Data from United Kingdom

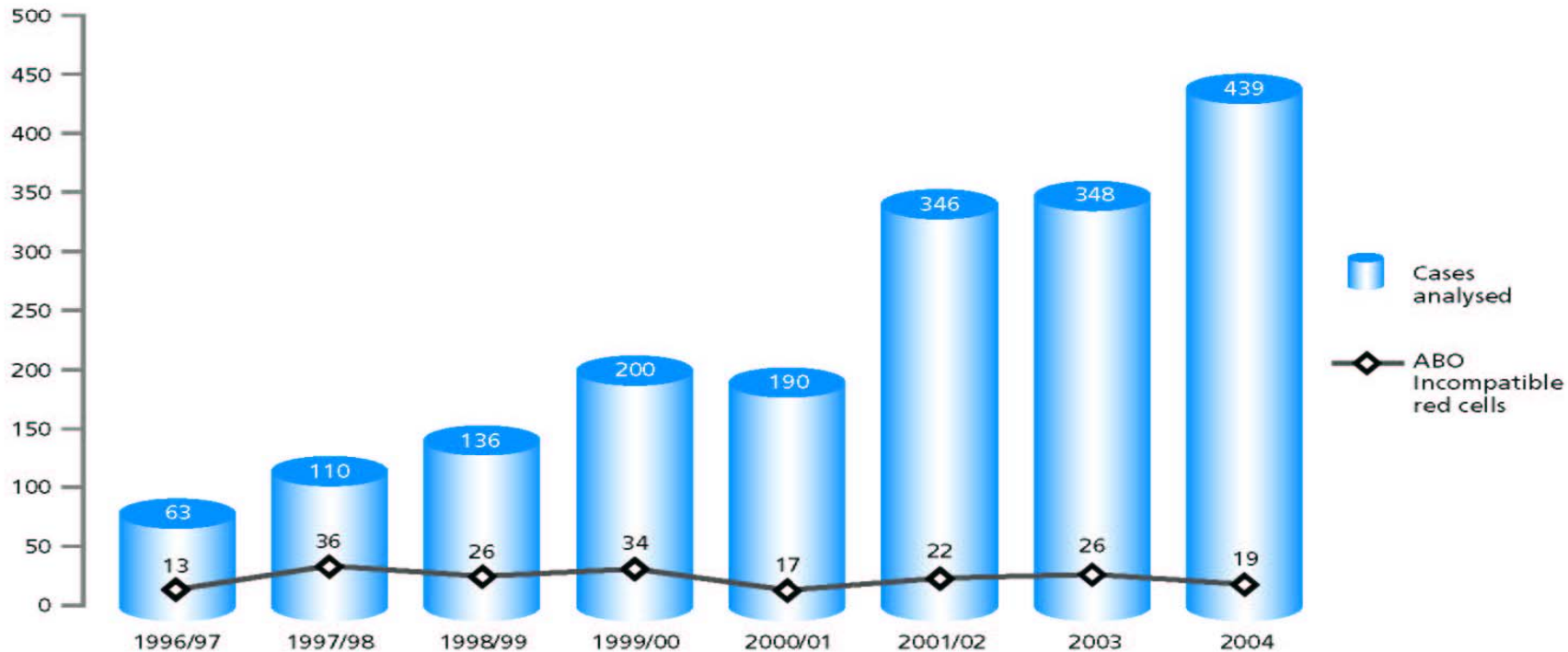
Questionnaires analysed



What Can Be Learned?

Data from United Kingdom

ABO incompatible red cell transfusions



U.S. Reports of Hemovigilance Data

- 2005 Nationwide Blood Collection & Utilization Survey (HHS) for the year 2004
 - 32,128 transfusion related adverse reactions
 - Reported by 1,322 medical treatment facilities
 - 160 events reported as TRALI
 - 52 ABO incompatibilities reported



Biovigilance in the U.S.

- HHS Strategic Plan – Biovigilance
- May 2006 ACBSA Meeting
- Interorganizational Discussions
 - Definition
 - Vision
 - Purpose



Interorganizational Biovigilance Discussions

- Public / private participation
 - Government
 - HHS
 - CDC
 - NHLBI
 - FDA
 - Blood collection / transfusion medicine community
 - AABB
 - ABC
 - ARC



Interorganizational Biovigilance Task Force U.S. Biovigilance Network

Vision:

To design and implement a comprehensive biovigilance system in the United States that will improve the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, cells, tissues and organs.



Advancing Transfusion and
Cellular Therapies Worldwide

www.aabb.org

U.S. Biovigilance Network

Purpose:

The Biovigilance Interorganizational Task Force will establish a comprehensive system to collect, analyze and report on the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, cells, tissues and organs to provide an early warning system for adverse events and to continuously improve donor and recipient safety.



Interorganizational Biovigilance Task Force

Charges:

1. Determine goals and objectives
2. Determine essential characteristics
3. Establish necessary data elements
4. Establish system specifications
5. Establish timeline:
 - Pilot (2007)
 - Operational system (2009)
6. Standardize terminology and definitions
7. Identify workflow processes
8. Estimate costs; develop budget
9. Develop pilot system
10. Develop marketing and communications plan
11. Develop system for analysis and recommendations
12. Oversee implementation



Biovigilance Network Table of Organization

Biovigilance Network Task Force

AABB	ASA	NMDP	US:BSAAC
AATB	ASBMT	PPTA	US:CDC
ABC	ASH	Province of Quebec	US:CMS
Advamed	CAP	Transfusion Alliance	US:FDA
AHA	ISBT	UNOS	US:HRSA
ARC	JCAHO	US:AHRQ	US:NHLBI

Biovigilance Network Steering Committee (Phase I)

AABB	US:ACBSA
ABC	US:CDC
ARC	US:FDA
	US:NHLBI

Met: July 11

Biovigilance Network Working Group

James AuBuchon, MD, chair	Cassandra Josephson, MD
Neil Blumberg, MD	Nancy McCombie
Rodeina Davis	Barbara Rabin-Fastman
Anne Eder, MD, PhD	Kent Sepkowitz, MD
Mark Fung, MD	Tait Stevens, MD
Linda Hahn	Barbee Whitaker, PhD, staff

Biovigilance Network International Correspondents

Georges Andreu, MD (Fr)	Mickey Koh, MD (SG)
Simon Benson, MD (NZ)	Mike Murphy, MD (UK)
Emer Lawlor, MD (Irl)	Pierre Robillard, MD (Can)
Paul Strengers, MD (ISBT)- <i>invited</i>	

Scheduled:
September 19

w (Electronic communications) **b.org**



Critical Elements to a U.S. Biovigilance Network

- Public/private partnership
 - Development
 - Implementation
- Clear and simple reporting
 - Non-punitive
 - Non-burdensome
- Pre-determined common definition for data elements
- Funding?



Critical Elements to the U.S. Biovigilance Network

- Confidential
- Data elements consistent w/other international systems but standardized on US practice of transfusion medicine
- Data analysis plan
 - Clear benefit to hospitals and patients
 - Forum for discussion of analysis
 - Opportunity for peer to peer exchange



U.S. Biovigilance Network

- AABB committed to working with Interorganizational Task Force
 - Public/private joint effort
 - Hospitals and blood centers
- Beneficial outcome to patients and donors alike

