United Blood Services

16th International Haemovigilance Seminar

Barcelona, Spain
March 2014

Layered data reporting allows DonorHART™ to meet a variety of donor vigilance needs: The first annual report of the AABB US Donor Hemovigilance System.

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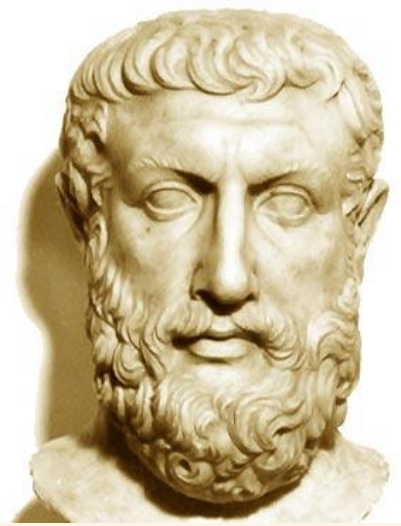
Chair, US Donor Hemovigilance WG
Senior MD, Blood Systems

Ontology and data structure modeling is not new

Taxonomies/Ontologies explain our conceptualization (understanding) of the world while information models (of data structures) describe and constrain how the data is stored and transmitted in messages.

- Thomas Gruber *"A Translation Approach to Portable Ontology Specifications"*:

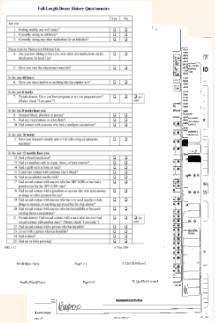
Principal questions of ontology:
"What can be said to exist?"
"Into what categories, if any, can we sort existing things?"
"What are the meanings of being?"
"What are the various modes of being of entities?"

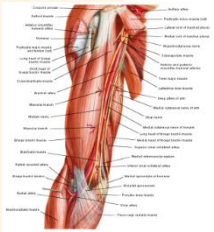


Parmenides, 5th BCE

Parmenides, was among the first to propose an ontological characterization of the fundamental nature or reality of things

Useful data surrounds the donation process and should be “freed” to improve donor experience & outcome





Who benefits from data freed from its primary donor suitability and component manufacturing use? The donor, others, but ultimately the Patient

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But without a way to organize the data
we are easily overwhelmed by the sheer volume of it

‘I wonder…if we haven't become so numbed by all these numbers that we are no longer capable of truly assimilating any knowledge which might result from them.‘ -Michael Lewis, Moneyball (2004)

	mon	tue	wed	thu	fri	mean	min	max	std dev	max vs mean
AA	58,999,240	72,381,152	42,096,336	69,050,024	41,012,568	56,707,864	41,012,568	72,381,152	14689029.4	27.64%
AXP	5,467,597	5,913,412	8,149,724	6,362,437	10,660,769	7,310,788	5,467,597	10,660,769	2131640.72	45.82%
BA	4,397,343	4,443,521	5,923,814	4,029,157	4,558,410	4,670,449	4,029,157	5,923,814	728150.945	26.84%
BAC	185,150,656	211,226,976	200,263,312	158,793,344	282,493,760	207,585,610	158,793,344	282,493,760	46265859.2	36.09%
CAT	4,154,455	5,302,793	5,697,076	4,538,329	4,573,074	4,853,145	4,154,455	5,697,076	628514.012	17.39%
CSCO	40,646,376	38,339,632	40,604,612	34,991,000	35,176,356	37,951,595	34,991,000	40,646,376	2780197.42	7.10%
CVX	6,848,664	7,822,791	7,840,545	5,720,456	5,563,772	6,759,246	5,563,772	7,840,545	1097334.71	16.00%
DD	12,533,999	10,044,324	6,550,408	5,408,238	4,502,440	7,807,882	4,502,440	12,533,999	3376512.02	60.53%
DIS	8,772,518	6,494,770	9,578,417	7,079,308	5,214,792	7,427,961	5,214,792	9,578,417	1755193.43	28.95%
GE	62,976,416	46,439,032	54,510,612	44,790,604	42,235,624	50,190,458	42,235,624	62,976,416	8494931.68	25.47%
HD	9,825,519	12,408,530	8,959,159	10,700,573	13,844,170	11,147,590	8,959,159	13,844,170	1974742.99	24.19%
HPQ	12,971,387	24,978,916	14,378,633	13,117,575	15,343,951	16,158,092	12,971,387	24,978,916	5025834.96	54.59%
IBM	3,633,350	4,163,471	3,994,942	3,443,314	4,546,899	3,956,395	3,443,314	4,546,899	436082.418	14.93%
INTC	51,406,808	64,413,640	53,302,272	103,593,920	154,888,736	85,521,075	51,406,808	154,888,736	44118755.7	81.11%
JNJ	9,690,132	7,307,541	8,312,000	9,467,186	11,274,671	9,210,306	7,307,541	11,274,671	1498773.79	22.41%
JPM	30,069,028	27,997,196	39,626,664	42,084,328	86,983,736	45,352,190	27,997,196	86,983,736	24038599.4	91.80%
KFT	5,462,785	6,619,107	6,225,670	6,646,924	6,005,374	6,191,972	5,462,785	6,646,924	489155.824	7.35%
KO	7,452,209	7,751,942	7,108,636	8,970,839	6,320,957	7,520,917	6,320,957	8,970,839	970856.165	19.28%
MCD	11,338,533	8,658,780	10,376,558	14,508,154	10,571,327	11,090,670	8,658,780	14,508,154	2146764.72	30.81%
MMM	3,475,188	3,024,365	2,732,457	2,351,599	2,094,220	2,735,566	2,094,220	3,475,188	545254.661	27.04%
MRK	10,723,631	10,234,515	12,878,902	74,286,608	41,751,400	29,975,011	10,234,515	74,286,608	28083717.4	147.83%
MSFT	57,538,608	50,298,880	52,623,048	66,978,236	62,691,184	58,025,991	50,298,880	66,978,236	6910938.72	15.43%
PFE	112,445,168	32,582,856	26,467,984	45,896,316	30,093,884	49,497,242	26,467,984	112,445,168	35945589.2	127.17%
PG	12,253,651	9,624,154	10,147,531	9,898,973	10,948,680	10,574,598	9,624,154	12,253,651	1060819.9	15.88%
T	41,334,980	57,318,424	36,029,048	35,897,648	34,192,520	40,954,524	34,192,520	57,318,424	9532562.31	39.96%
TRV	4,212,917	3,224,613	3,796,245	3,333,056	3,797,952	3,672,957	3,224,613	4,212,917	399664.082	14.70%
UTX	3,301,579	3,474,512	3,233,676	2,693,905	4,632,643	3,467,263	2,693,905	4,632,643	713838.175	33.61%
VZ	38,467,204	43,272,532	24,845,974	23,885,186	22,160,384	30,526,256	22,160,384	43,272,532	9642139.75	41.76%
WMT	10,478,403	12,022,847	13,552,224	12,865,256	9,286,738	11,641,094	9,286,738	13,552,224	1745821.32	16.42%
XOM	20,766,330	15,804,717	17,361,868	20,437,044	23,478,852	19,569,762	15,804,717	23,478,852	3021394.44	19.98%

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There are many stakeholders of data & its analysis

Futball example: Player Roster

- Who benefits?
  Players, parents, managers

GOALKEEPING STATISTICS	
NUM	NAME
1	Victor Valdés
13	José Manuel Pinto
25	Olazábal
OUTFIELD STATISTICS	
NUM	NAME
3	Gerard Piqué
4	Cesc Fábregas
16	Sergio Busquets
9	Alexis Sánchez
7	Pedro
8	Andrés Iniesta
6	Xavi
10	Lionel Messi
22	Dani Alves

21	Adriano
14	Javier Mascherano
11	Neymar
2	Martin Montoya
18	Jordi Alba
15	Marc Bartra
17	Alex Song
5	Carles Puyol
20	Cristian Tello
24	Sergi Roberto
28	Adama Traore
19	Ibrahim Afellay
29	Jean Mario Dongou
12	Jonathan Dos santos
27	Patri

There are many stakeholders of data & its analysis

Team Standings

Minimum Data Set

Additional information understood within a broader context

Who primarily derives value?

Fans, governance body, bookies

Liga BBVA
Standings

#	Team	GP	W	D	L	GF	GA	GD	PTS
1	Real Madrid	26	20	4	2	73	26	47	**64**
2	Atlético Madrid	26	19	4	3	61	21	40	**61**
3	Barcelona	25	19	3	3	70	20	50	**60**
4	Athletic	26	15	5	6	49	30	19	**50**
5	Villarreal	26	13	5	8	47	31	16	**44**
6	Real Sociedad	25	12	7	6	46	35	11	**43**
7	Levante	26	9	9	8	26	31	-5	**36**
8	Valencia	25	10	5	10	38	36	2	**35**
9	Sevilla	25	9	8	8	43	41	2	**35**
10	Espanyol	26	9	6	11	29	32	-3	**33**
11	Celta Vigo	26	8	6	12	32	37	-5	**30**
12	Osasuna	26	8	5	13	24	39	-15	**29**
13	Elche	26	7	8	11	23	37	-14	**29**
14	Granada	26	8	3	15	22	36	-14	**27**
15	Getafe CF	26	7	6	13	23	40	-17	**27**
16	Málaga	26	6	8	12	24	35	-11	**26**
17	Almería	25	7	5	13	24	42	-18	**26**
18	Valladolid	26	4	11	11	28	44	-16	**23**
19	Rayo	25	6	2	17	25	59	-34	**20**
20	Real Betis	26	3	6	17	21	56	-35	**15**

High level data

Great for overall high level status (eg surveillance)

Suggests additional information needed to predict success

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There are many stakeholders of data & its analysis

Comparisons and Predictions require granular data from many sources

Who primarily derives value?

Managers, clubs, fans, countries, media, statisticians, financiers

#	Name / Position	Age	Foot	Height	Nat.	In the team since	Before	Market value
1	Victor Valdés Keeper	32	right	1,83		2002 to 2014		12.000.000 €
13	José Manuel Pinto Keeper	38	right	1,85		2008 to 2014		300.000 €
25	Oier Olazábal Keeper	24	left	1,89		2013 to 2015		800.000 €
3	Gerard Piqué Centre Back	27	right	1,92		2008 to 2015		36.000.000 €
5	Carles Puyol Centre Back	35	right	1,78		1999 to 2016		1.000.000 €
14	Javier Mascherano Centre Back	29	right	1,74		2010 to 2016		15.000.000 €
15	Marc Bartra Centre Back	23	right	1,83		2012 to 2017		12.000.000 €
18	Jordi Alba Left-Back	24	left	1,70		2012 to 2017		25.000.000 €
21	Adriano Left-Back	29	both	1,72		2010 to 2017		15.000.000 €
2	Martín Montoya Right-Back	22	right	1,74		2012 to 2014		12.000.000 €
22	Dani Alves Right-Back	30	right	1,73		2008 to 2015		18.000.000 €
16	Sergio Busquets Defensive Midfield	25	right	1,89		2008 to 2018		45.000.000 €
17	Alex Song Defensive Midfield	26	both	1,84		2012 to 2017		18.000.000 €
6	Xavi Central Midfield	34	right	1,70		1998 to 2016		10.000.000 €
8	Andrés Iniesta Central Midfield	29	right	1,71		2002 to 2018		55.000.000 €
12	Jonathan dos Santos Central Midfield	23	right	1,72		2012 to 2015		3.000.000 €
24	Sergi Roberto Central Midfield	22	right	1,77		2013 to 2015		8.000.000 €
4	Cesc Fàbregas Attacking Midfield	26	right	1,79		2011 to 2016		50.000.000 €
19	Ibrahim Afellay Left Wing	27	right	1,80		2012 to 2015		5.000.000 €
11	Neymar Left Wing	22	both	1,75		2013 to 2018		60.000.000 €
20	Cristian Tello Left Wing	22	both	1,78		2012 to 2018		9.000.000 €
7	Pedro Right Wing	26	both	1,69		2007 to 2016		25.000.000 €
9	Alexis Sánchez Right Wing	25	right	1,69		2011 to 2016		30.000.000 €
23	Isaac Cuenca Right Wing	22	both	1,79		2012 to 2015		3.000.000 €
10	Lionel Messi Centre Forward	26	left	1,69		2004 to 2018		120.000.000 €
		Average age: 27,3 Years			Total: 223.100.000 €			ø-MV: 23.524.000 €

More complex and granular data

Comes from many sources (from many data owners)

Dynamically changes

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There are many stakeholders of data & its analysis

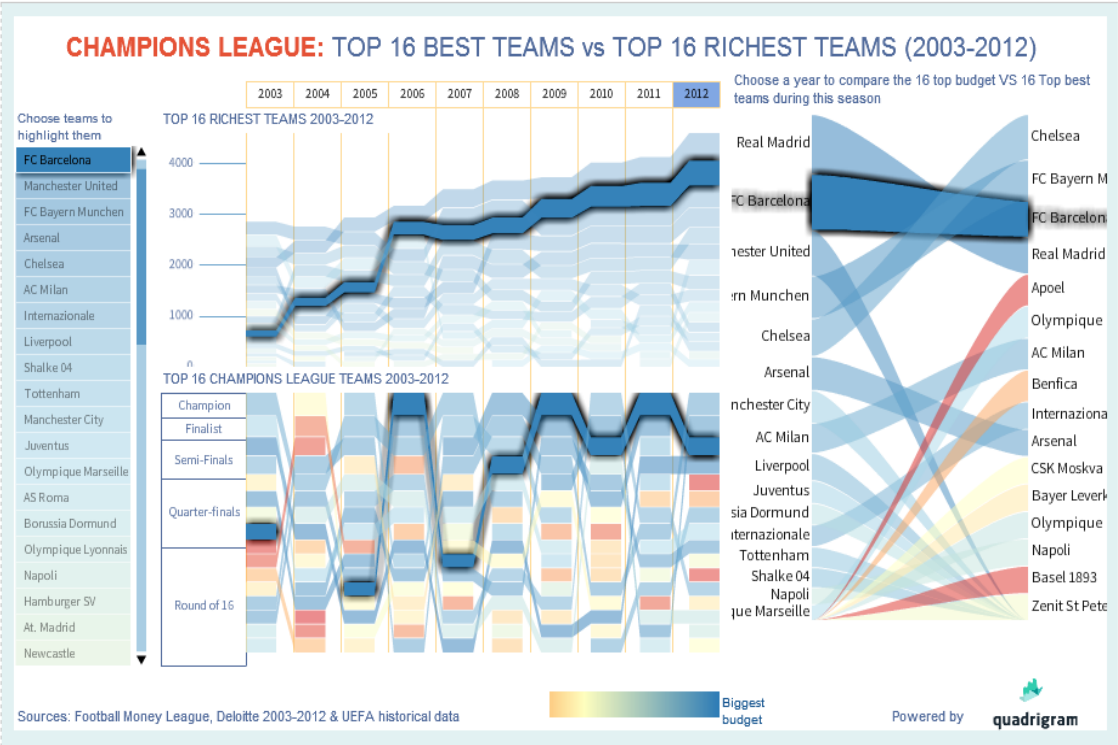
The same data is used and viewed in dramatic ways

Who primarily derives value?

All stakeholders for different reasons

Summary of predictions — *Probability of….*

				Score	Home Win	Draw	Away win
Real Madrid	2 - 0	Real Zaragoza		15%	87%	10%	3%
Real Sociedad	0 - 2	FC Barcelona		17%	5%	13%	82%
Deportivo La Coruña	1 - 1	Atlético Madrid		12%	45%	25%	30%
Levante UD	1 - 0	Sporting Gijón		16%	50%	28%	22%
Málaga CF	1 - 0	Hércules CF		15%	42%	30%	28%
Racing Santander	1 - 0	RCD Mallorca		13%	48%	27%	25%
UD Almería	0 - 1	Sevilla FC		10%	28%	22%	50%
Villarreal CF	2 - 0	Getafe CF		17%	75%	18%	7%
Osasuna	1 - 0	Valencia CF		12%	49%	26%	25%
D Espanyol	2 - 1	Athletic Bilbao		10%	52%	23%	25%



Explain what has happened and predict what may continue to happen

Requires access to variety of data and ongoing refinement of models/ideas

Not possible within the context of minimum data set alone

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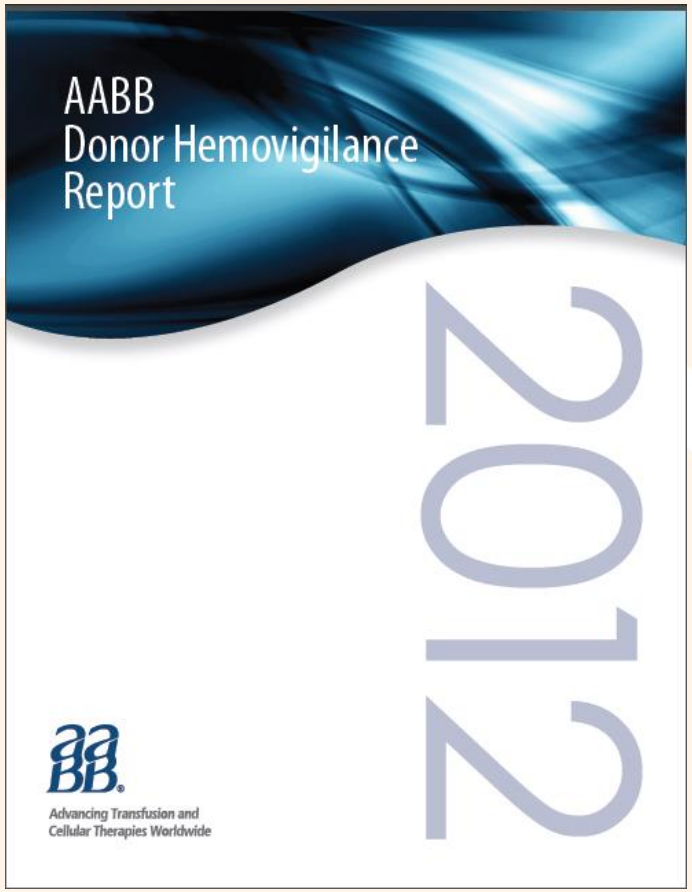
Donor Safety is universal!

- Appropriate donation type, frequency, minimum Hgb, & volume
  - Male versus Female donors
  - Estimated total blood volume
  - Annual Blood and Plasma loss

- Reducing events and reactions
  - Young versus older donors
  - First time versus repeat donors
  - Prompt Identification & Treatment
  - Falls and Injuries
  - Preventions & Interventions
  - Iron or Calcium depletion
  - Increasing donor satisfaction/return rate

US Donor Hemovigilance Working Group



- HISTORY:
  - WG began in 2007 as a public-private partnership
  - Desired to support variety of stakeholders
  - Initially validated by 3 facilities
- GOALS:
  - Develop a US DHV **common definition set (CDS)** based on
    - Existing and models, both nationally and internationally.
    - Objective evidence-based criteria, signs and symptoms
    - A voluntary, secure, non-punitive system.
  - International CDS standard with defined minimal (MDS) & optional data elements

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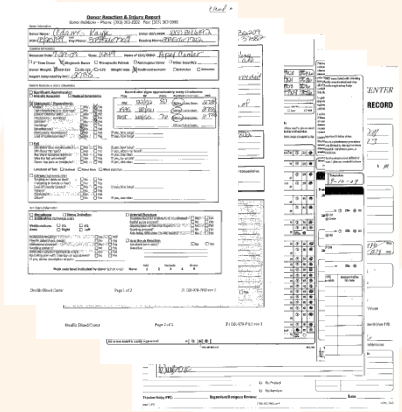
AABB First Donor Hemovigilance Annual Report: 2012 data

- Adverse reactions from 1,171,906 individual donations
- Denominator Data: 100% univariant
- 99% Allogenic donations (1% total autologous, directed, and therapeutic)
- 148 Potential data + 80 univariant denominator data elements

Q: How long does it take to report?
A: Time allocation ~ 3 ¾ hrs/mo

- IT Data download (≤1h)
  - electronic reaction information
  - denominator data

- DHV file manual data entry (2.5h)
  - Initially, additional documentation from forms added ~15m per record.
  - Reduced to <5 min each or ~ 15 reports/hr in <1mo use



- Upload to DHV website (<15m)

- Initially took 6h/mo longer
  - Now takes same time as before, with more data for analysis

Q: What type of data elements are gathered?
A: Reaction Type & Category + optional signs &symptoms

Table Reaction Example	
Reaction Type	Reaction Category
Vasovagal	Prefaint, no LOC (uncomplicated or minor)
	LOC, any duration (uncomplicated)
	LOC, any duration (complicated)
	Injury
Local Injury related to needle	Nerve Irritation
	Hematoma/Bruise
	Arterial Puncture
Apheresis	Citrate
	Hemolysis
	Air Embolus
Allergic	Local
	Systemic
	Anaphylaxis
Other	Other

Q: How much data do you report?
A: Not all of it…by design

2012-2103 (~22 facilities in the cue)

- 5 facilities reported 2012 data
- 2 other facilities with partial data
- 8 in contract talks
- 7+ adopting CDS

Table X: Attribute Reporting	
Donor Variable	Percent reporting
Age	100%
Donation History	100%
Donation Type	100%
Gender	100%
Procedure Type	100%
Ethnicity	80%
Collection Site	80%
Pulse	60%
Sponsor Group Type	60%
Weight	60%
Blood Pressure	40%
Race	40%
Device Manufacturer	20%
Device Model	20%
Height	20%
Device Software	0%
Container Manufacturer	0%
Container Kit Type	0%

Q: How much data do you report?
A: Not all of it…by design

	Total Elements	Minimum required	Allows null	Min Elements
Donor Data	7	4	3	Organization name, Donor ID, DOB, gender
Donation Data	36	5 (2 + 3)	31	Organization name, Donor ID, Collection Center, Donation ID, Donation Date
Reaction Data	25	7 (2+2 + 3)	18	Organization name, Donor ID, Collection Center, Donation ID, Reaction Type, Reaction Category, update-flag

+ 80 elements in Denominator Data

Courtesy Pilot Facility Bonfils Blood Center, Denver Co
United Blood Services

Q: How accessible is the requested data?
A: Initial gap shows all data is not readily available.

	Total Unique Elements (% avail)	Inform. System* (BECS)	Primary Forms	Not Collected	Not Relevant	Initially Reported to DHV (%)
Donor	7 (100%)	7	0	0	0	7 (100%)
Donation	34 (46%)	12	7	12 (height/ manufact/kit)	3 (total protein/ Hgb)	12 (35%)
Reaction	21 (83%)	0	21 +1 update flag	0	0	10 (48%)
Total	62 (64%)	31%	44%	19%	6%	29 (47%)

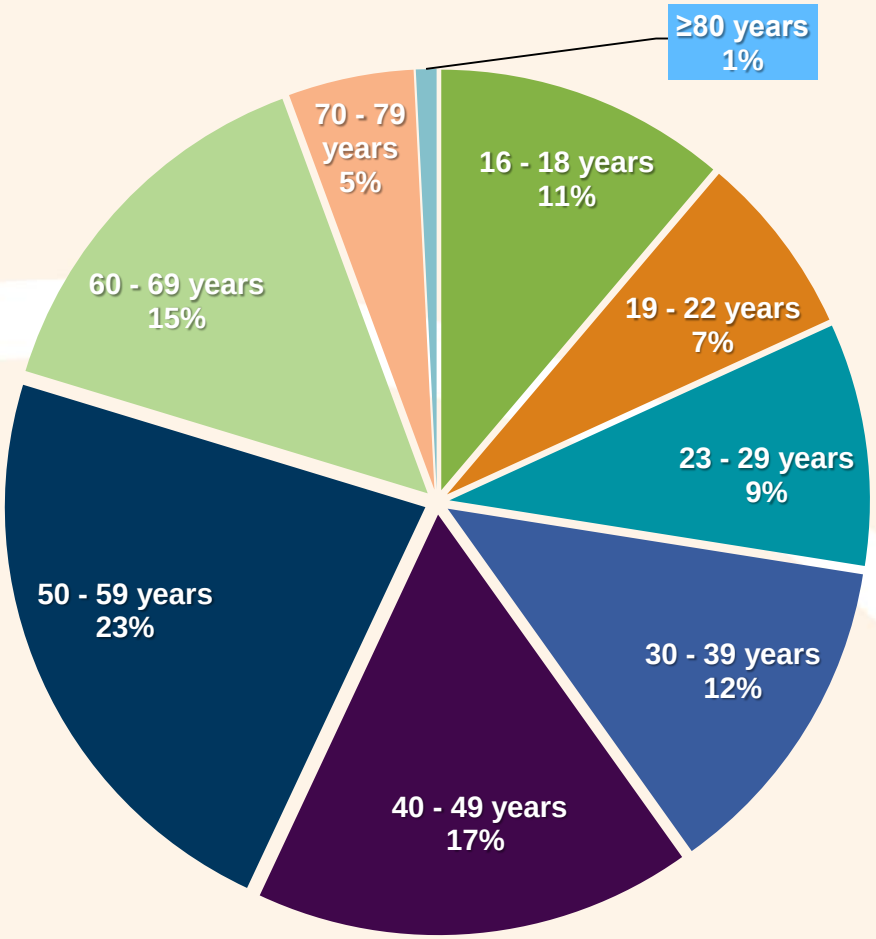
Primary Forms: Included on DN Incident Form, Donation Record, or Apheresis Run Sheet
Not Relevant: Not intended for our business (eg total protein)

Donor Demographics (n=1,171,906 individual donations)

Attribute	Donation %	Reaction %	Reaction %/ Donation%
GENDER			
Female	**47.9**	**65**	**1.36**
Male	**52.1**	**35**	**0.67**
Donation Status			
First Time Donor	**14.6**	**31.3**	**2.14**
Repeat Donor	**85.4**	**68.7**	**0.80**
Donation Type			
Whole Blood	**75.5**	**83.6**	**1.11**
Automated*	**24.5**	**16.4**	**0.67**

*Aph PLT 14.2%, dRBC 14.2%, PLT & RBC 1.2%, PLT & Plasma 1.6 %, other multi-comp 1.7%

Donations by Donor Age



≥40yo = 61%

≥60yo = 21%

High School = 11%

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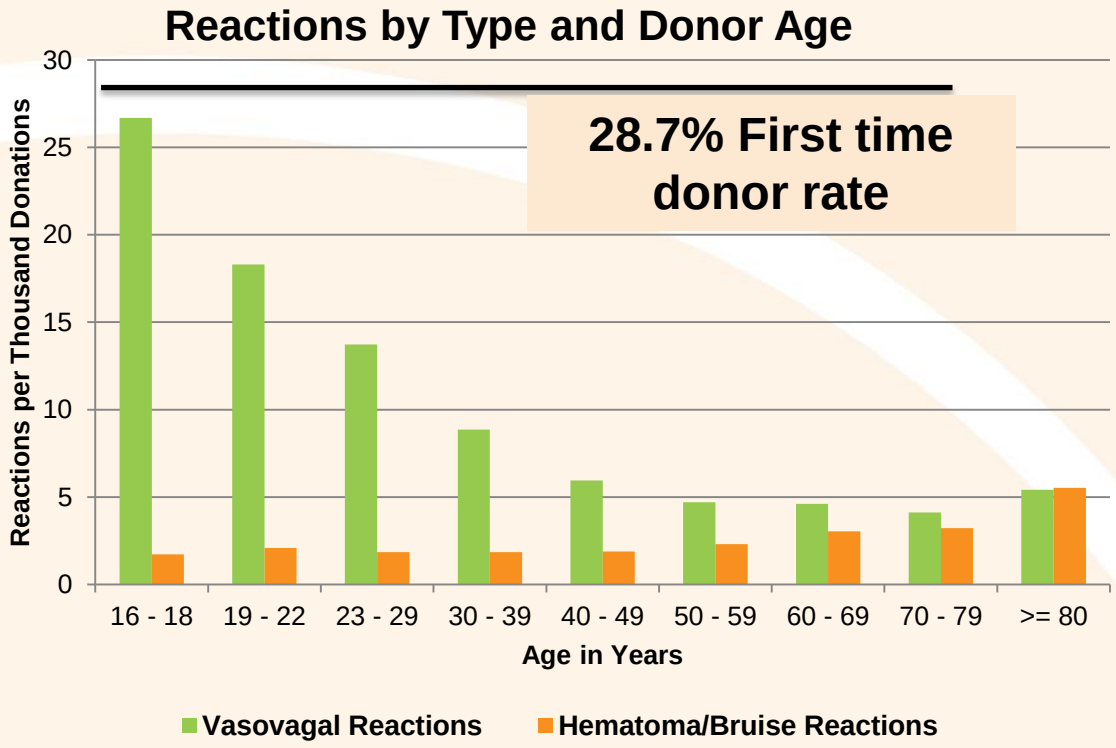
Reactions By Type and Donor Age



Age	Reaction rate for all reactions types per 1,000 Donations (all p<0.001)*
16 - 18 years	29.7 (2.28)*
19 - 22 years	22.2 (1.69)
23 - 29 years	17.2 (1.3)
30 - 39 years	12.0 (0.91)
40 - 49 years	9.3 (0.7)
50 - 59 years	8.7 (0.65)
60 - 69 years	9.3 (0.7)
70 - 79 years	9.0 (0.67)
≥80 years	12.3 (0.93)

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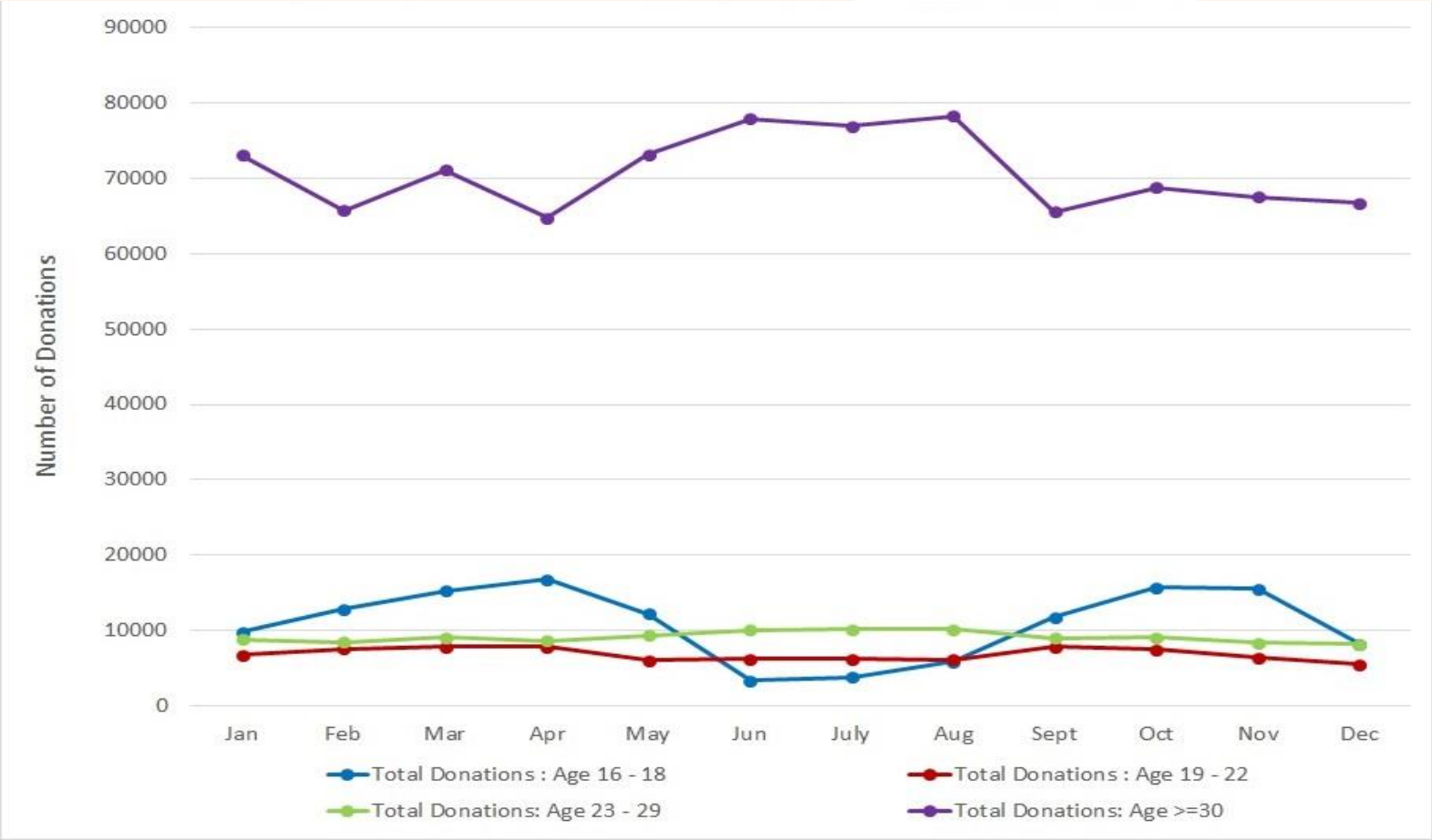
Surveillance Type Reaction Rate Summary Table per 1,000 donations

	Reaction rate	Odds Ratio	Lower 95% CI	Upper 95% CI
Overall Reaction Rate	13.41			
Vasovagal	**9.65**			
Prefaint, no LOC (uncomplicated or minor)	7.33	1.00	1.00	1.00
LOC, any duration (uncomplicated)	1.87	0.25	0.24	0.27
LOC, any duration (complicated)	0.4	0.05	0.05	0.06
Injury	0.06	0.01	0.01	0.01
Local Injury related to Needle	**2.48**			
Nerve Irritation	0.23	0.10	0.09	0.12
Hematoma / Bruise	2.23	1.00	1.00	1.00
Arterial Puncture	0.03	0.01	0.01	0.02
Apheresis	**0.83**			
Citrate	0.05	0.06	0.05	0.08
Hemolysis	0	0.01	0.00	0.01
Air Embolus	0	0.00	0.00	0.01
Infiltration	0.77	1.00	1.00	1.00
Allergic	**0.22**			
Local	0.18	1.00	1.00	1.00
Systemic	0.04	0.20	0.14	0.28
Anaphylexis	0	0.00		
Other	**0.23**			

Seasonal Donation Patterns Among Donors



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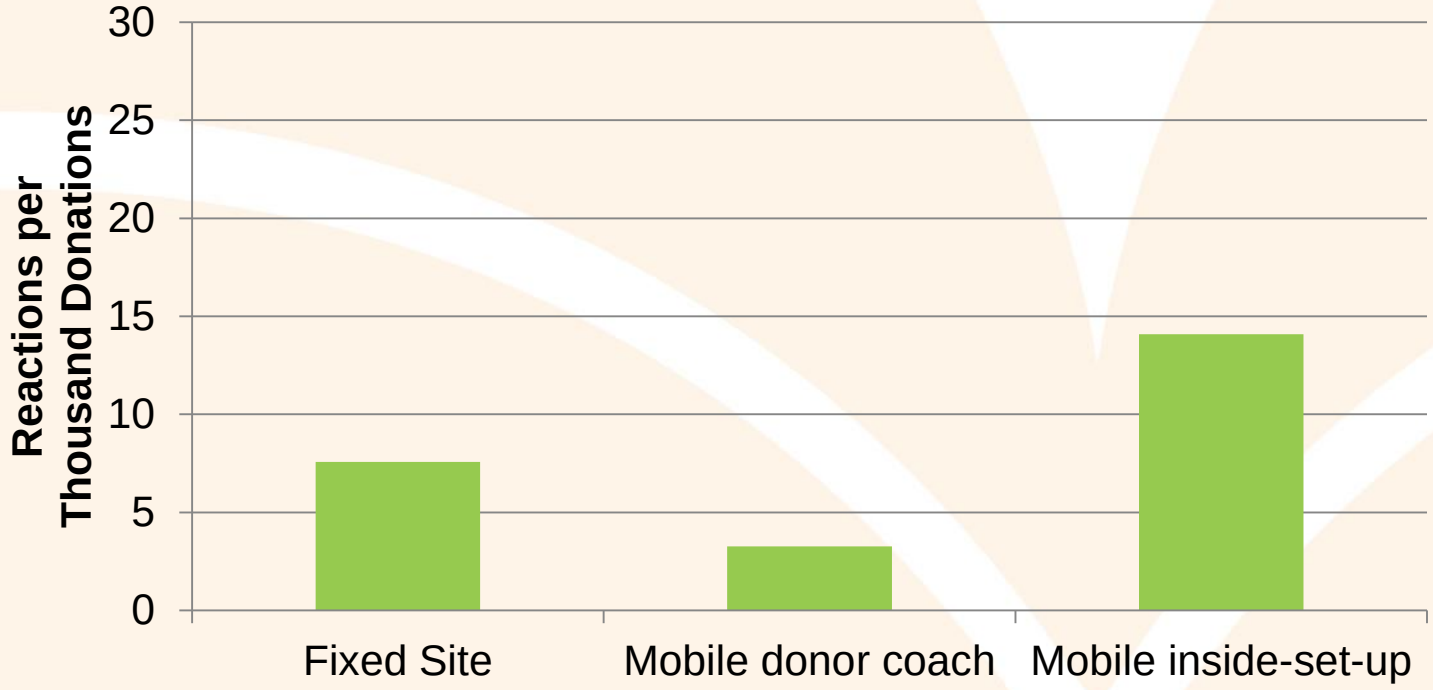
Reaction Rate by Collection Site
Potential limitations of univariant analysis



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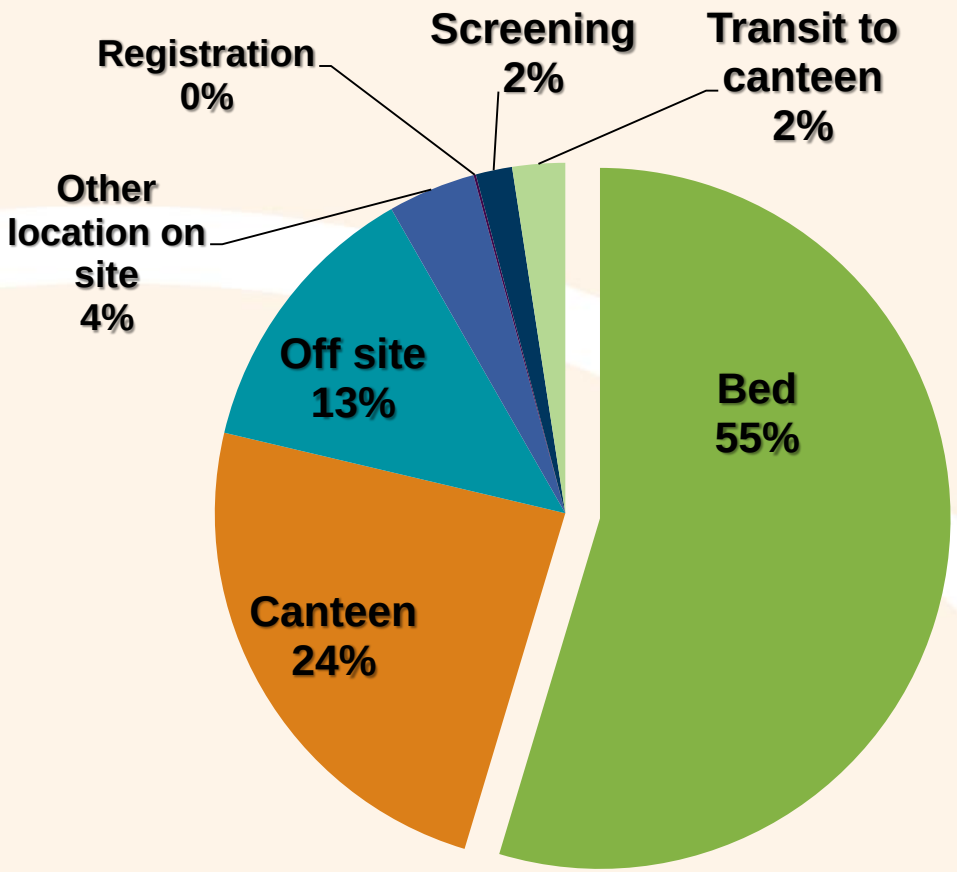
Reactions by Location



- 2% Pre-donation
- 55% While on bed
- 43% Post-donation
  6% walking onsite
  4% in bathroom
  13% offsite

United Blood Services

Collection Facilities are Discovering Additional and Innovative Uses for their DHV Data

- Medical Affairs (Assessing post implementation effectiveness of risk reduction strategies)
  - Implementation of pre-hydration stations and salt replacement initiatives
  - Restriction of blood donations based on new total blood volume calculation
  - Impact of staff tension training on donor adverse events
- Quality Assurance (As part of a quality essentials program)
  - Comparison of facility reaction rates to national aggregate results
  - Denominator data helps identify statistical sampling size needed for auditors
- Operations
  - Impact on donor adverse events as a result of pure operational changes
    - Changes in bag size and manufacturer (450ml – 500ml)
    - New mobile double red cell collection program
    - New staff monitoring for high risk donor groups (eg high school blood drives)
  - Descriptive denominator data being used for marketing and recruitment
- Business Review Made Easy (Standard DonorHART™ reports are used)

Current and Future Directions of AABB Donor HV

- Continued alignment with international DHV definitions (New Charge)
  - Help develop thoughts around both Minimum Data Set (MDS) and larger Common Definition Set (CDS)
- Formally define DonorHART™ Lite
- Implement bi-variant and multi-variant denominator data capabilities
- Begin DHV research projects, such as…
  - impact of Iron and Calcium depletion in donors

International Donor Vigilance Efforts: Evolving how Collection Centers view their data

Stage	Description	Benefits
I	Internal data collection	Local data gathering and research
II	Internal adoption of external standard vocabulary	Ability to compare your data to others based on internationally accepted vocabularies
III	Surveillance data (aka minimal data set)	•Minimal common surveillance data that can be shared and compared internationally •Surveillance detail summarized in AABB annual report
IVa	Basic Benchmarking (aka DonorHART lite)	•Data incorporated into AABB donor hemovigilance annual report •Donor hemovigilance dashboard
IVb	Enhanced Benchmarking with extended data mining capability (use of common definition set)	•Shared process improvement expertise to improve donor outcomes •Increased BECS data liquidity (donor demographics, business analytics, etc)

Final thought…

Who knows how future generations will be inspired by our freed data

Thank you!

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