Ten years of TRIP reporting: what has it brought us?

Johanna (Jo) Wiersum-Osselton

TRIP national coordinator *and*

senior donor physician, Sanquin (part time)

- Rise of hemovigilance
- Donor (hemo)vigilance:
  - Whole blood donation
  - Peripheral blood stem cells
- “Recipient” hemovigilance
  - Infectious complications
  - Antibodies
  - TRALI
  - Errors
- Vigilance in different areas: integration or fragmentation?
- Strengths and limitations of HV data; where next?

Hemovigilance (HV)

a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence

De Vries et al, Haemovigilance: an effective tool for improving transfusion practice. Vox Sanguinis (2011)

Hemovigilance: is it making a difference to safety in the transfusion chain?

Johanna C. Wiersum-Osselton

Yes and no

1994	France
1996	SHOT (Serious Hazards of Transfusion)
2003	European Haemovigilance Seminar in Amsterdam TRIP (Transfusion Reactions in Patients)
	Other systems already active: Ireland, Denmark (DART), Québec, Greece …
2008	First year of mandatory EU hemovigilance reporting
2010	~~European~~ International Haemovigilance Network
2011	WHO survey on blood safety 2008; 164 countries responded 57 countries have national HV system 62 countries collect 99-100% from voluntary unpaid donors In 39 countries blood is not routinely tested for TTIs

Transfusion chain

DONOR	Blood component	Hospital blood transfusion laboratory	Clinical transfusion practice	**PATIENT**

Question from a colleague

In 2009 we were asked, “What rate of donor complications do you see? Could we share experiences?”

Sanquin
Blood Supply

Measures and advances

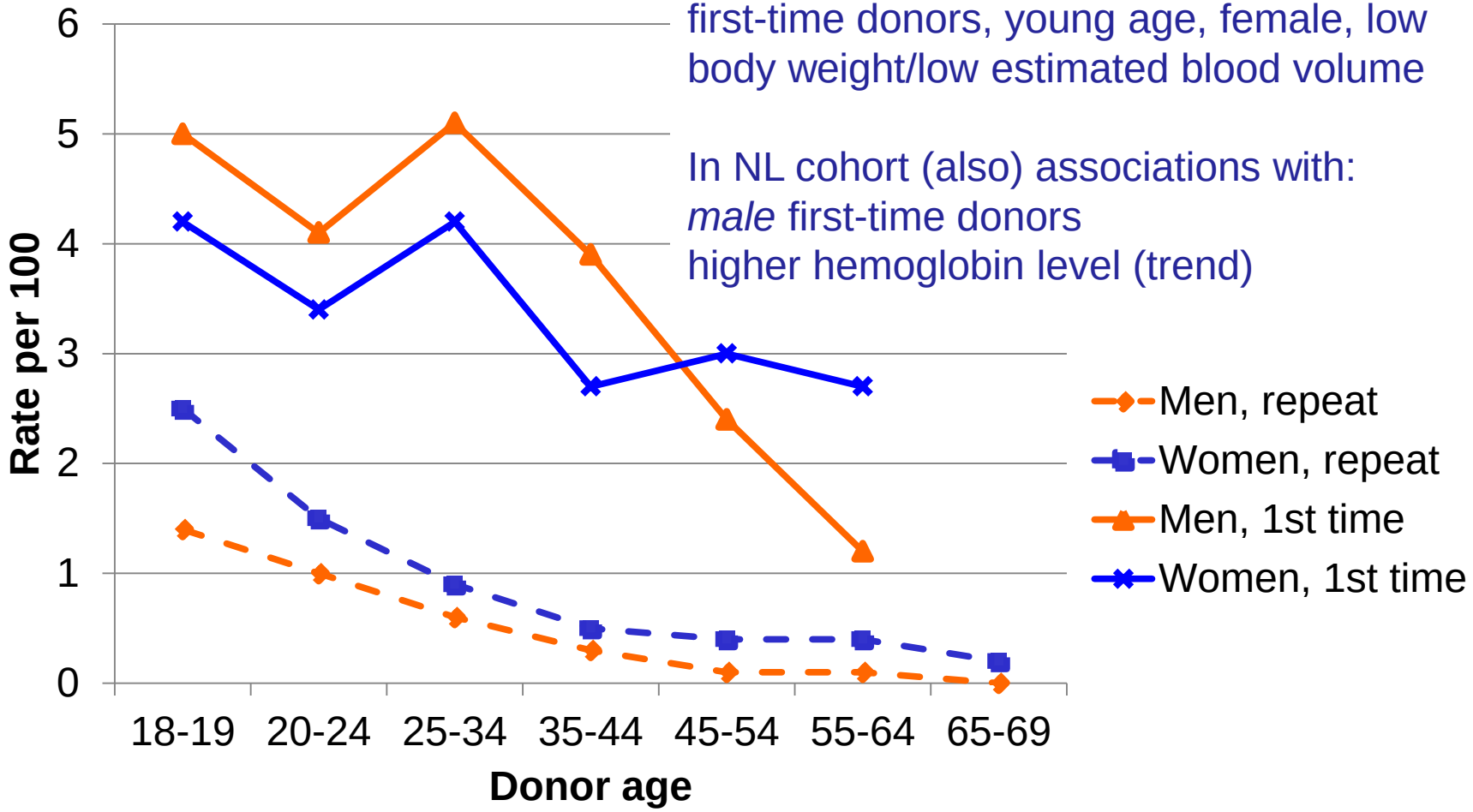
- SOP revised
- New codes in 2010
  - donor complications and procedural problems
- Staff recertification in venepuncture technique
- IV solutions: extra precautions to prevent mix-up of citrate and saline
- Quarterly review of rates per collection centre (initiated mid 2010)

Vasovagal reactions

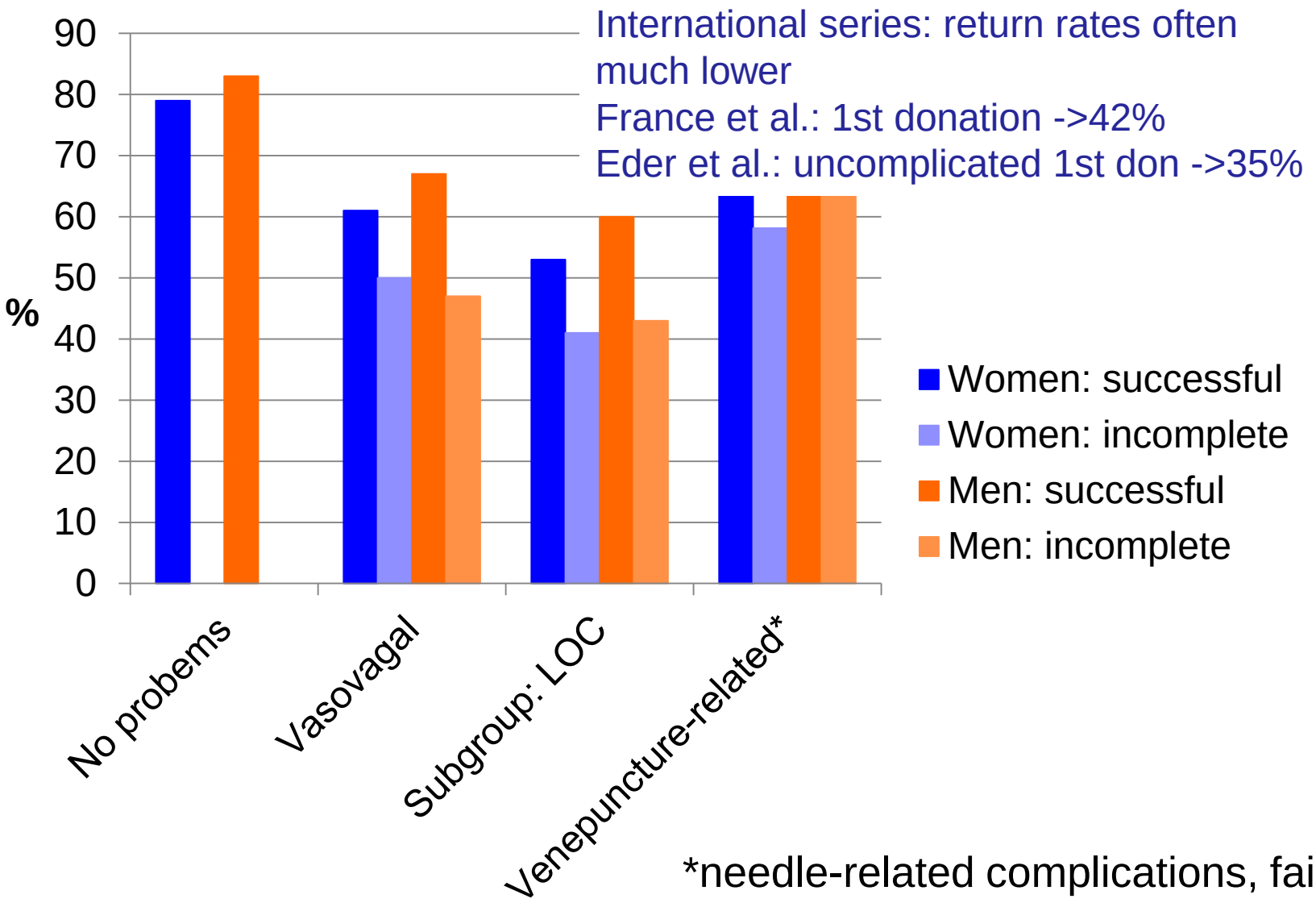
Whole blood donations in 2010, total n=551744 (5.2% from first-time donors)

Risk factors for vasovagal reactions: first-time donors, young age, female, low body weight/low estimated blood volume

In NL cohort (also) associations with:
male first-time donors
higher hemoglobin level (trend)



Complications and donor return
(First-time whole blood donors, 2010)



International series: return rates often much lower
France et al.: 1st donation ->42%
Eder et al.: uncomplicated 1st don ->35%

LOC = loss of consciousness

*needle-related complications, failed stab or flow problems

Using vigilance data to improve quality/safety

- Feedback to collection centres
- Pre-donation information to donors
- Possible interventions
  - Providing information on avoiding complications (France 2010)
  - Pre-donation water drink (Newman 2007)
  - Muscle tensing (France 2009)
  - Salty snack (Wieling 2011)
  - Social support (Hanson 2009)
  - Collection volume <-> donor's estimated blood volume (Eder 2011, young donors)

Peripheral blood stem cell (PBSC) donation Related donors in LUMC, 1996-2006

Background to study:

- 2004: introduction of PBSC collections from unrelated donors (Sanquin – Europdonor)
- Increasing use internationally
- Theoretical concern about use of growth factors: potential increase of hematologic malignancy / auto-immune disease

N=268

- Pilot study for prospective study including unrelated donors
- **Retrospective review** of routinely recorded data (case notes, lab results, FU normally to 1y)
- **Medical questionnaire** sent (from 2008)
- Special focus on subgroup who would have been deferred as unrelated donors (n=40, 13%) by international criteria

Serious problems during mobilisation or associated with harvest

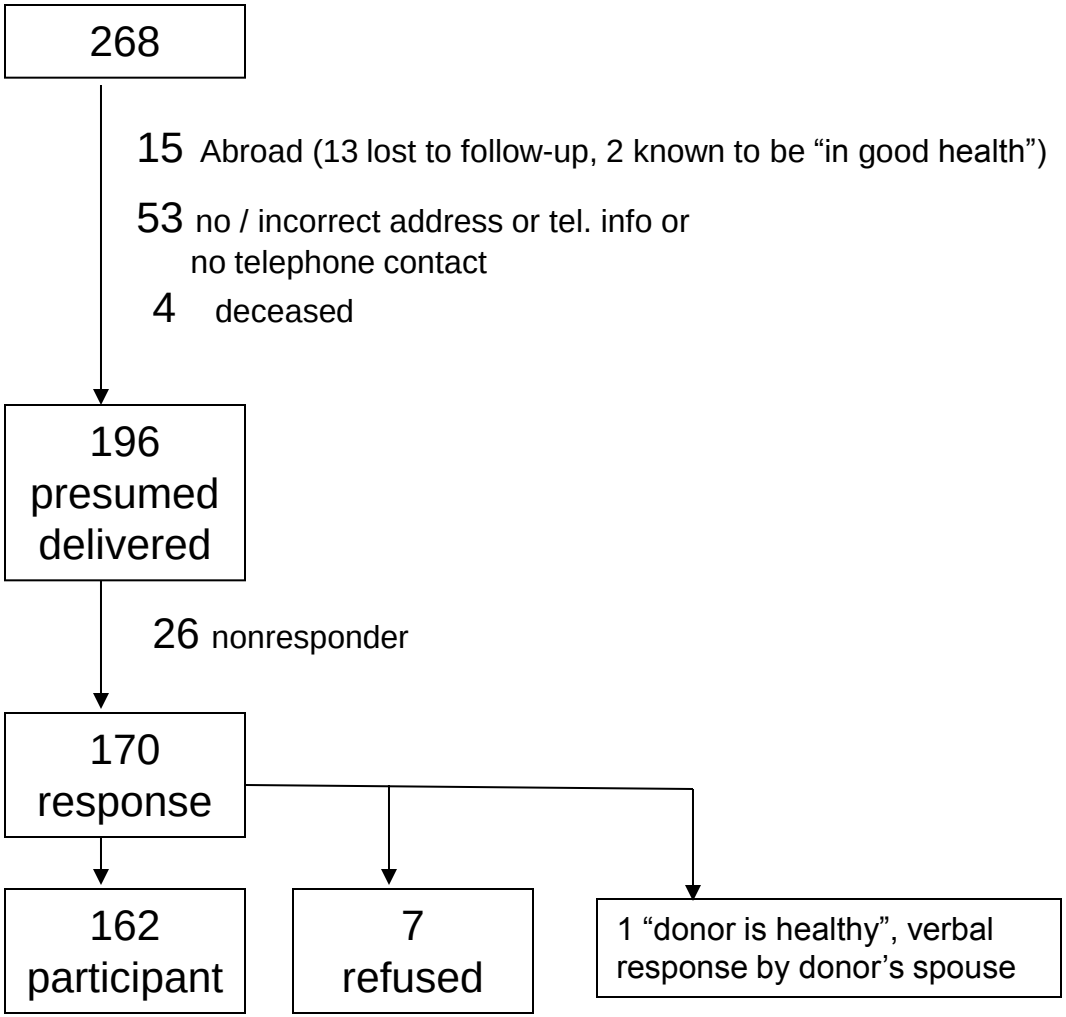
Problem		Deferrable
Excessive tiredness, 1d hospital admission	M, 32y	Bp
Chest pain, investigated, no specific pathology	F, 34y	-
Severe pain, 1d hospital admission, opiates	M, 38y	BMI, bp
Inguinal vein thrombosis after central venous catheter	F, 45y	-
Chronic pain at G-CSF injection sites	F, 24y	-
5/268=1.9% (95% CI 0.2 – 3.5%) similar to published rates		
Potentially serious dose incidents		
Received incorrect G-CSF dose; no excessive rise in WBC	F, 36y	Previous deep venous thrombosis
No dose reduction day 3 (WBC was 80 x 10^9/L); pre-collection WBC 107 x 10^9/L.	F, 55y	Previous deep venous thrombosis

BMI=body mass index (>40 kg/m^2)
Bp=raised blood pressure (>160/90 mm Hg)

Sanquin Bloedvoorziening

LUMC

Questionnaire sent average 7 years after procedure



Overall participation 61%

~female, older donors

83% when address confirmed

Standardised morbidity ratio (SMR)

http://statline.cbs.nl/statweb/
http://www.iknl.nl

	Events	Person years at risk	Incidence rate (IR) per 1000 person years (95% CI)	Expected IR	SMR (95% CI)
Cardiovascular					
Eligible	7	1080	6.5 (2.5-12.3)	11.5	0.6 (0.2-1.1)
Deferrable	7	156	44.9 (17.4-85.2)	33.3	1.3 (0.5-2.6)
Malignancy					
Eligible	5	1086	4.6 (1.4-9.6)	3.9	1.2 (0.4-2.5)
Deferrable	4	167	24.0 (6.0-53.9)	10.2	2.4 (0.6-5.3)

No increase of incidence (even in deferrable group)

Eligible group is at lower cardiovascular risk

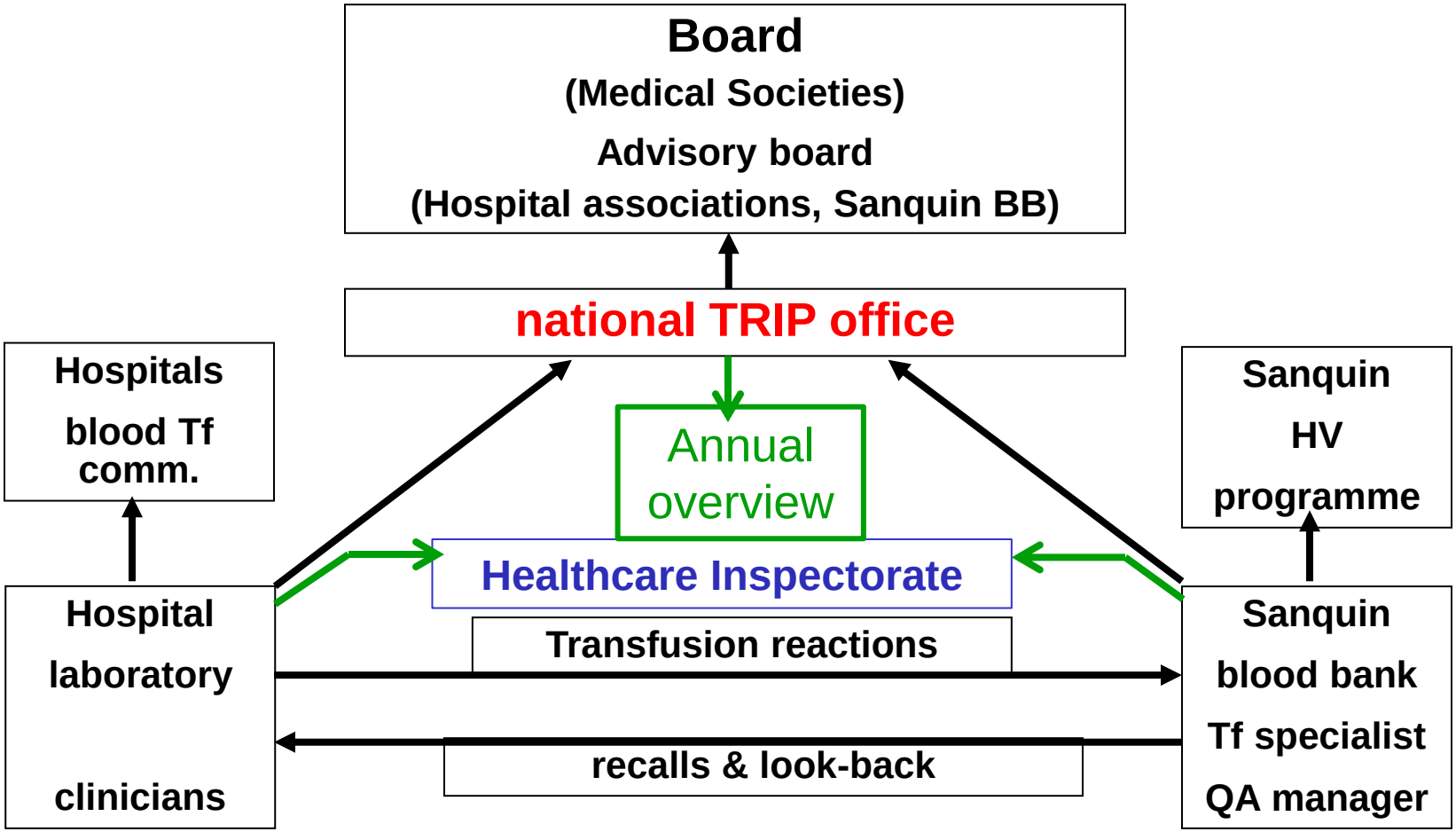
Sanquin
Bloedvoorziening

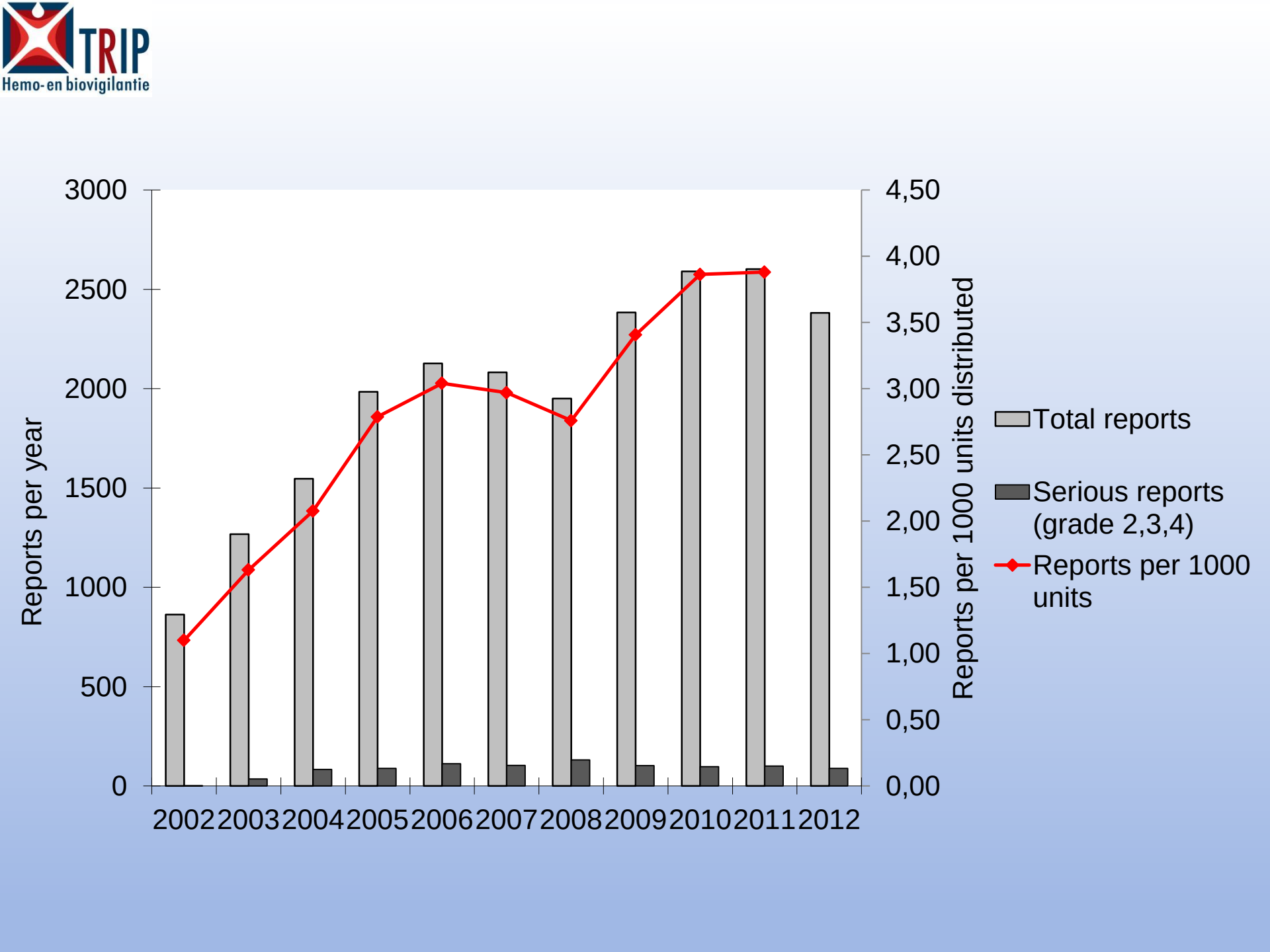
Comment

- Use of criteria for unrelated donation effectively selects (cardiovascular) lower-risk population
  ->implement for related donors?
- Related stem cell donors: lack of funding for long-term FU
- Difficulty obtaining response also encountered by other groups
- FU needed for all donors
  ->safety profile documented

Recipient hemovigilance

TRIP foundation




TRIP
Hemo-en biovigilantie
Reports per year
3000
2500
2000
1500
1000
500
0
Reports per 1000 units distributed
4,50
4,00
3,50
3,00
2,50
2,00
1,50
1,00
0,50
0,00
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
Total reports
Serious reports (grade 2,3,4)
Reports per 1000 units

Hemovigilance data and bacterial contamination

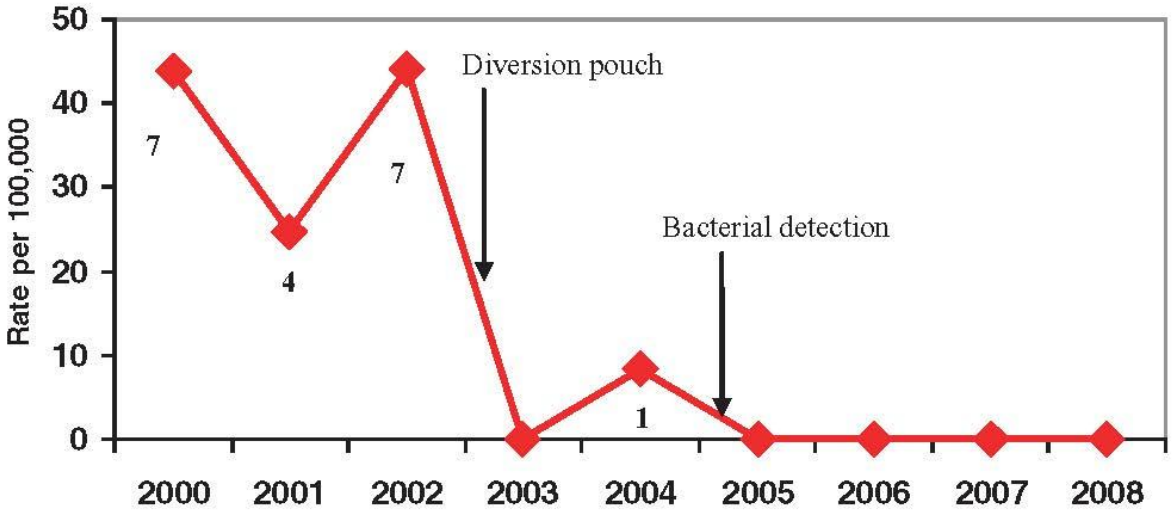


Fig. 1. Annual incidence of TTBIs per 100,000 pools of 5 units of WBDPs. The number of cases and time of implementation of preventive measures are shown on the graph.

Robillard P et al, Transfusion 2011; 51:1405-11

Use of hemovigilance data to evaluate the effectiveness of diversion and bacterial detection (Québec)

In NL:
bacterial screening, diversion pouch and improved skin preparation introduced in 2001

After introduction of diversion the number of positive screening cultures [of platelet concentrates] decreased significantly from 0.85% to 0.37%.
De Korte D et al, Transfusion Med and Hemotherapy 2011; 38:251-254

swissmedic

Bacterially contaminated PC 2005-10

Year	Severity	Imputability	Pathogen	Transfused on day
2005	4	certain	E.coli	4
	4	certain	E.coli	5
	3	certain	P. fluorescens	3
	3	certain	P. fluorescens	4
	1	probable	Coagulase neg Staph *	2
2006	1	certain	Strep. salivarius	5
2007	1	probable	Strep. mitis	4
	1	certain	Coagulase neg Staph	4
2008	1	probable	Coagulase neg Staph	4
	3	probable	Coagulase neg Staph	1
2009	4	certain	Klebsiella pneumoniae	5
	3	certain	Klebsiella pneumoniae	5
	3	certain	E.coli	3
2010	3	certain	Bacillus cereus	5

* +Abiotrophia adjacens, Haemophilus parainfluenz.

IHS 2011, Amsterdam

M. Ruesch, IHS Amsterdam 2011

Overall risk (14/19)	1:11'000 / 1:8000 (incl. possibles)
Fatal reaction (3)	1:50'000

->Implementation of pathogen reduction

Switzerland: transfusion reactions associated with platelets

Transfusion reactions	**2009-2011 cPCs**		**2011 & 2012 PI-PCs**		**PCs TRIP 2011**
Units transfused	66,000		62,500		61665 distributed
	Reports	Rate per 1000	Reports	Rate per 1000	Rate per 1000
All definite / probable reports	223	3.4	160	2.5	2.2
Definite/ probable grade 3 reports	23	0.3	6	0.1	0.1
Septic transfusion reactions (n)	N=4		N=0		N=1

PC=platelet concentrate
cPC=conventional platelet concentrate
PI-PC=Intercept Pathogen-Inactivated platelet concentrates

M. Ruesch et al, IHS Brussels 2013

Transfusion reaction reports

Transfusion reactions	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
AHTR	12	8	14	9	19	11	18	18	21	15
Anaphylactic	13	8	21	26	19	54	65	71	73	65
Other allergic	98	132	171	219	222	202	171	181	184	189
Hemosiderosis				4	5	3	5	2	4	2
Mild NHFR	247	326	341	375	363	328	275	360	363	362
NHTR	240	318	345	435	490	452	453	488	505	497
New allo-ab	117	244	428	571	607	601	610	756	814	826
Other reaction	48	54	64	67	61	55	101	136	164	215
Post-tf bacteremia (before 2008: bacterial contamination)	12	9	5	10	7	19	37	55	41	60
Post-tf other infection										1
PTP	1						1			2
Post-tf viral infection	1	5	7	8	7	7	7	4	1	5
TA-GVHD							1			
TRALI	9	7	9	17	25	31	21	13	17	12
Delayed HTR	21	19	14	12	14	11	18	8	7	9
TACO	1	7	6	27	34	31	39	42	47	38

1-2 Transfusion-transmitted bacterial infections (TTBI) per year

TRIP 2002-2011

Virus	"Look-back",° no infection	Post-transfusion viral infection			Comment
		all imputa-bilities	probable or certain	possible	
Hepatitis B	79	15	6[#]	2	[#]Donations in 1993, 2006 and 2007 HBV NAT since autumn 2008
Hepatitis C	0	11	0	3	
B19	0	4	[$]1	[$]1	[$]Components not B19-safe; no investigation
CMV	0	12	2	5	No report confirmed
EBV	0	6	0	1	
HAV	0	1	0	0	Report in 2006, Tf in 2003, no investigation by Sanquin
HIV	4**	1	0	[§]1	[§]Report from 2003, unconfirmed **Recipients died, no clinical signs of HIV
HTLV	1	0	0	0	Recipient died, no clinical signs

° Reported to TRIP by hospital

Transfusion reaction reports

Transfusion reactions	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
AHTR	12	8	14	9	19	11	18	18	21	15
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NHTR	240	318	345	435	490	452	453	488	505	497
New allo-ab	117	244	**428**	**571**	**607**	**601**	**610**	**756**	**814**	**826**
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Post-tf viral infection	1	5	7	8	7	7	7	4	1	5
TA-GVHD							1			
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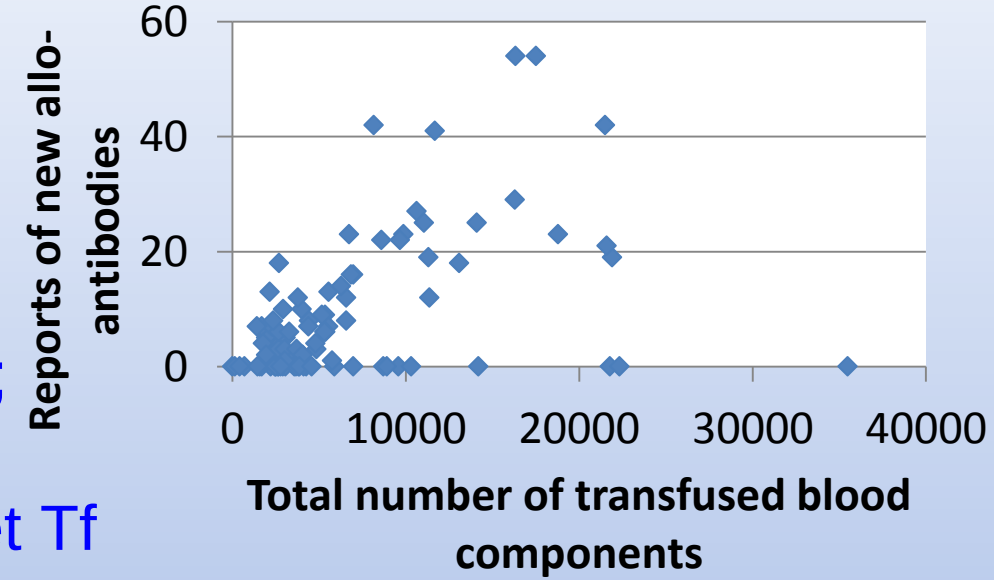
Allo-antibodies

- 32% of all reports; reported to TRIP by 61% of hospitals (2011)



- France: 2746

NL 2011: 36.1% of all reports;

1.5 0.8 per 1000 RBC:

0.5 0.5 per 1000 platelet Tf

- TRIP 2007: Rh phenotype compatibility recommendation for women of childbearing potential
- CBO guideline (2011): K neg (or compatible), c and E compatible RBC for women <45y

Allo-antibodies: case-control study in two hospitals

Table 4. Crude and adjusted odds ratios (OR; 95% confidence intervals) for association between patient characteristics and alloimmunization. Total n=188 in study, reports from 2003 – 2005 (May).

Patient characteristic	Crude OR	Confounder	Adjusted OR
Female sex	1.89 (1.05 to 3.38)	Diabetes mellitus; symptomatic atherosclerosis	1,74 (0.96 to 3.16)
Lymphoproliferative disorders	0.33 (0.13 to 0.81)	Chemotherapy within one month prior to alloimmunization; previous allogeneic haematopoietic stem cell transplantation	0.26 (0.09 to 0.71)
Previous allogeneic haematopoietic stem cell transplantation	2.24 (0.64 to 7.81)	Lymphoproliferative disorders; myelogenous marrow disorders; chemotherapy within one month prior to alloimmunization	3.70 (0.94 to 14.63)
Solid malignancy	2.07 (1.00 to 4.30)	Chemotherapy within one month before alloimmunization	2.13 (1.02 to 4.44)
Symptomatic atherosclerosis	0.52 (0.25 to 1.08)	Diabetes mellitus; female sex	0.46 (0.21 to 0.99)
Diabetes mellitus	2.15 (0.91 to 5.05)	Female sex; symptomatic atherosclerosis	2.66 (1.07 to 6.63)

Other work

- Schonewille 2008
  - Cohort of 5016 patients with 5981 antibodies
  - FY, JK, and MNS antibodies alone and in combination with anti-E and/or anti-K.
  - No support was found that response against strong RBC antigens enhances antibody formation against weaker antigens.
- Verduin 2012: is female sex a risk factor?
  - systematic review of 30 studies
  - Women with sickle cell disease at greater risk of allo-immunisation; no sex difference in other patient groups
- Zalpuri 2012 cumulative incidence of alloimmunization
  - Cohort of 3002 previously untransfused patients receiving not extensively matched RBC transfusion (n=31103 RBC)

  1·0% at 5 units, 2·4% at 10 units, 3·4% at 20 units and 6·5% at 40 units of RBC
- Koelewijn 2008
  - Severe HDFN, caused by antibodies other than anti-D, is associated with anti-K, anti-c, and to a lesser extent with other Rh-alloantibodies.

Risk factor =>
consider recommending extended matching

Transfusion reaction reports

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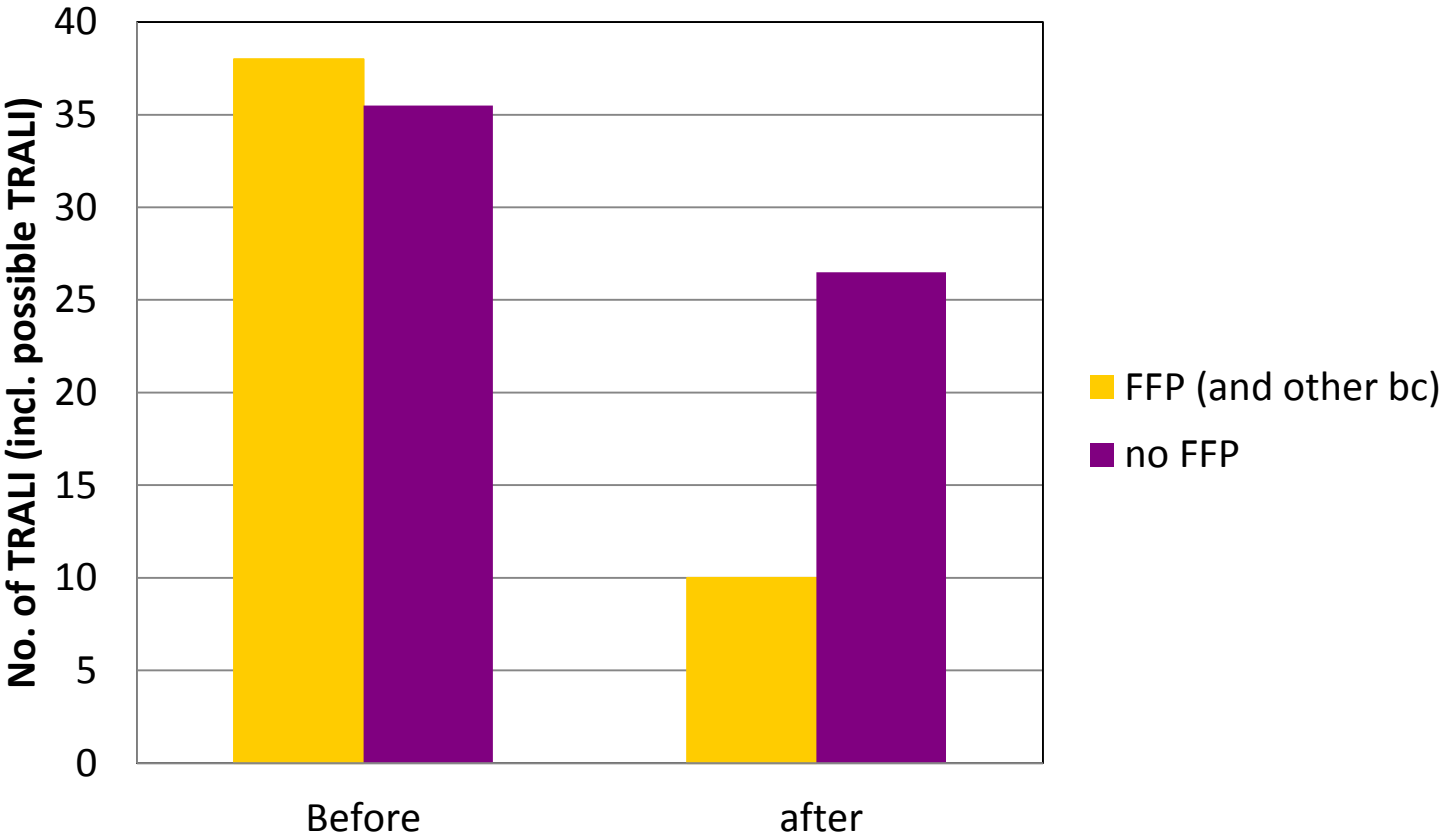
Male-only plasma supplied from mid 2007

Transfuson-related acute lung injury (TRALI): male-only plasma



Prior to change

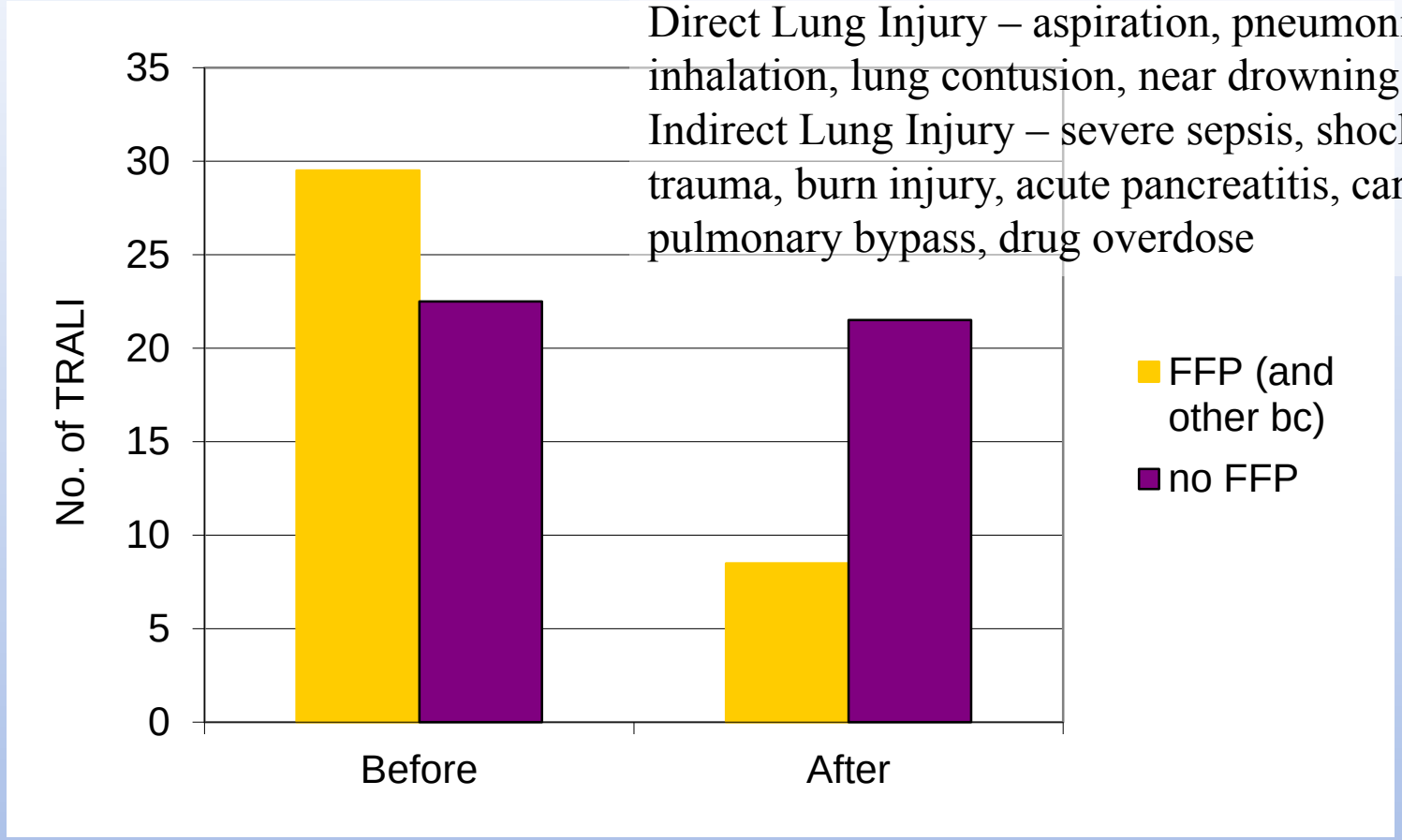
P.A.R. 0.33 (95% CI 0.09 – 0.51)

TRANSFUSION 2011;51:1278-1283.

TRALI (2)

International consensus definition:
"possible TRALI" = ALI within 6h of Tf,
in presence of other risk factors:

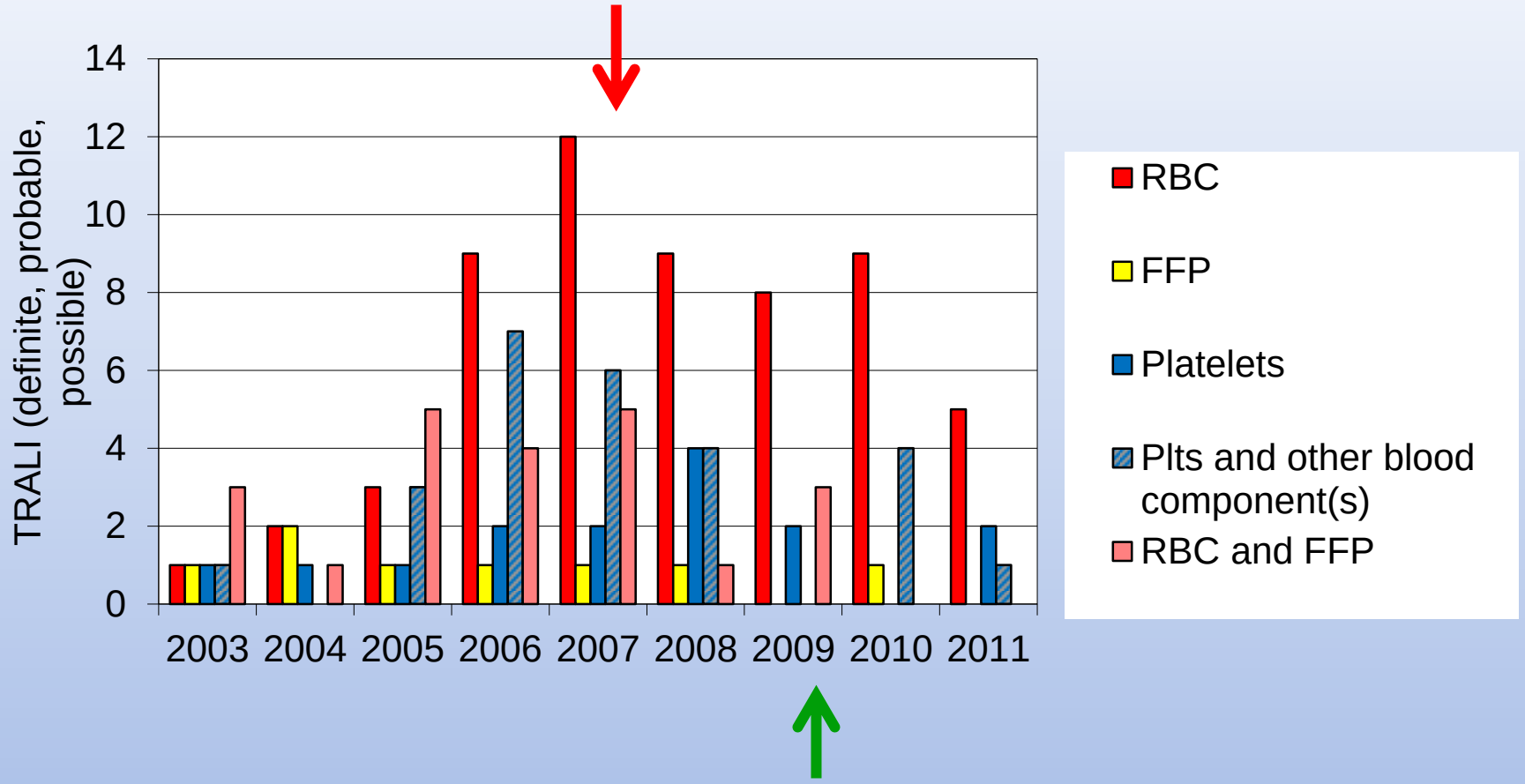
Direct Lung Injury – aspiration, pneumonia, toxic inhalation, lung contusion, near drowning
Indirect Lung Injury – severe sepsis, shock, multiple trauma, burn injury, acute pancreatitis, cardio-pulmonary bypass, drug overdose



After excluding cases of "possible TRALI"
P.A.R. 0.37 (0.06 – 0.58)

TRANSFUSION 2011;51:1278-1283.

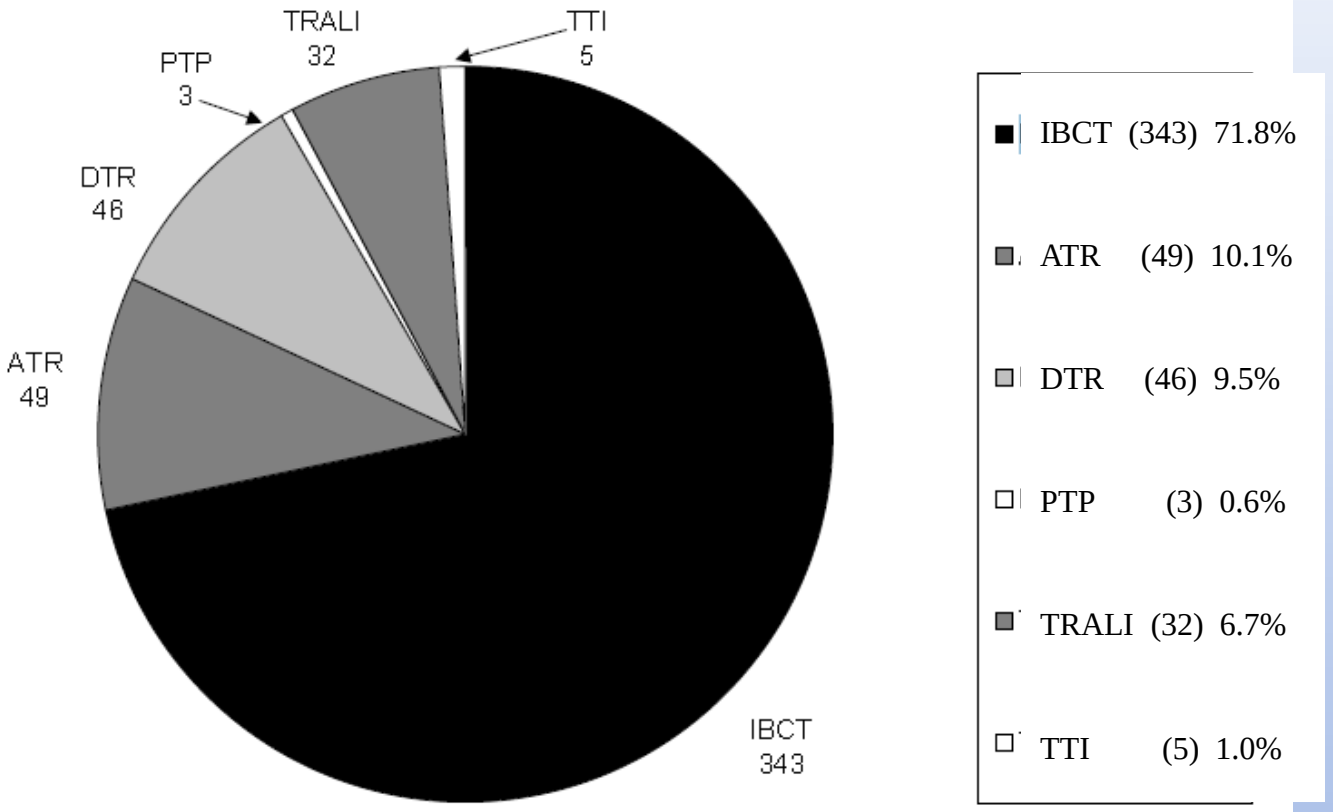
Blood components associated with TRALI (definite, possible, probable)



Platelet measure: male-only plasma added as storage solution for 5-D BC platelets in plasma

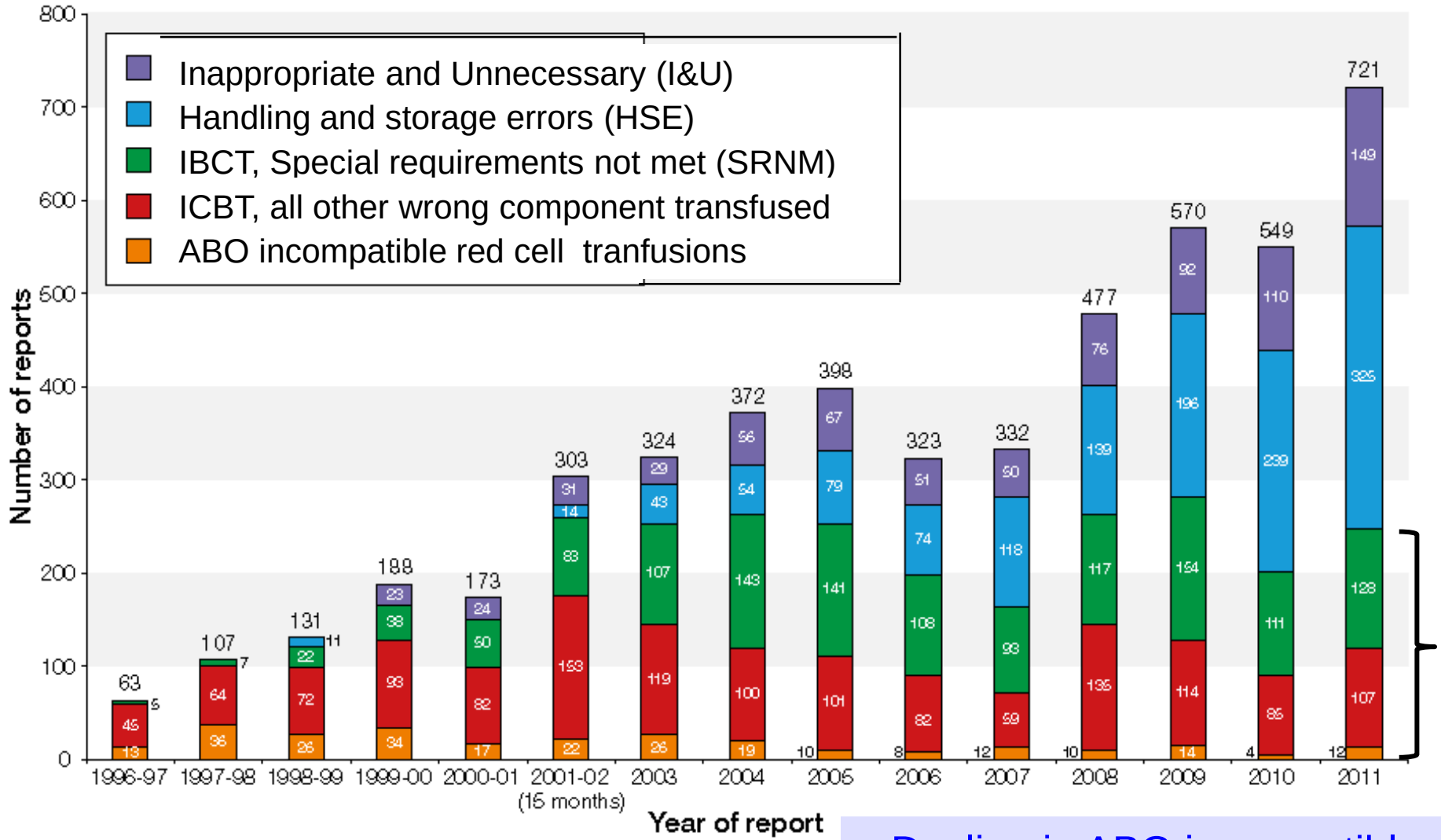
SHOT (Serious Hazards of Transfusion) report 2001-2

Figure 6
Overview of 478 cases for which initial reports were received over 15 months



Incorrect blood component transfused (IBCT)
72% of reports

Data from SHOT



Decline in ABO incompatible RBC transfusions

ABO incompatibility (France)

Decline in ABO incompatible RBC transfusions

France	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
RBC	20	14	13	7	12	9	9	10	9	6	8	3
plasma	5	4	1	0	1	0	0	0	0	0	0	2
platelets	3	2	7	5	4	5	3	4	4	5	6	4

Contrôle ultime of ABO compatibility at the bedside (since 1985); importance of verification of patient identity stressed by ministerial circular in 2003

Incident reports to TRIP

Incident reports	2003	2004	2005	2006	2007	2008	2009	2010	2011	Hosp. with reports (ever)
Incorrect blood component transfused	34	36	60	64	64	59	61	58	44	80
ABO-risk*#				17	15	20	29	14	16	59
ABO incompatible RBC transfusion#				6/5	5	6	12	4/3	4	31
Near miss	31	62	79	77	74	55	72	68	43	45
Other incident	5	12	51	86	100	83	110	117	137	61

*TRIP assessment (from 2006): worst risk to which patient was exposed

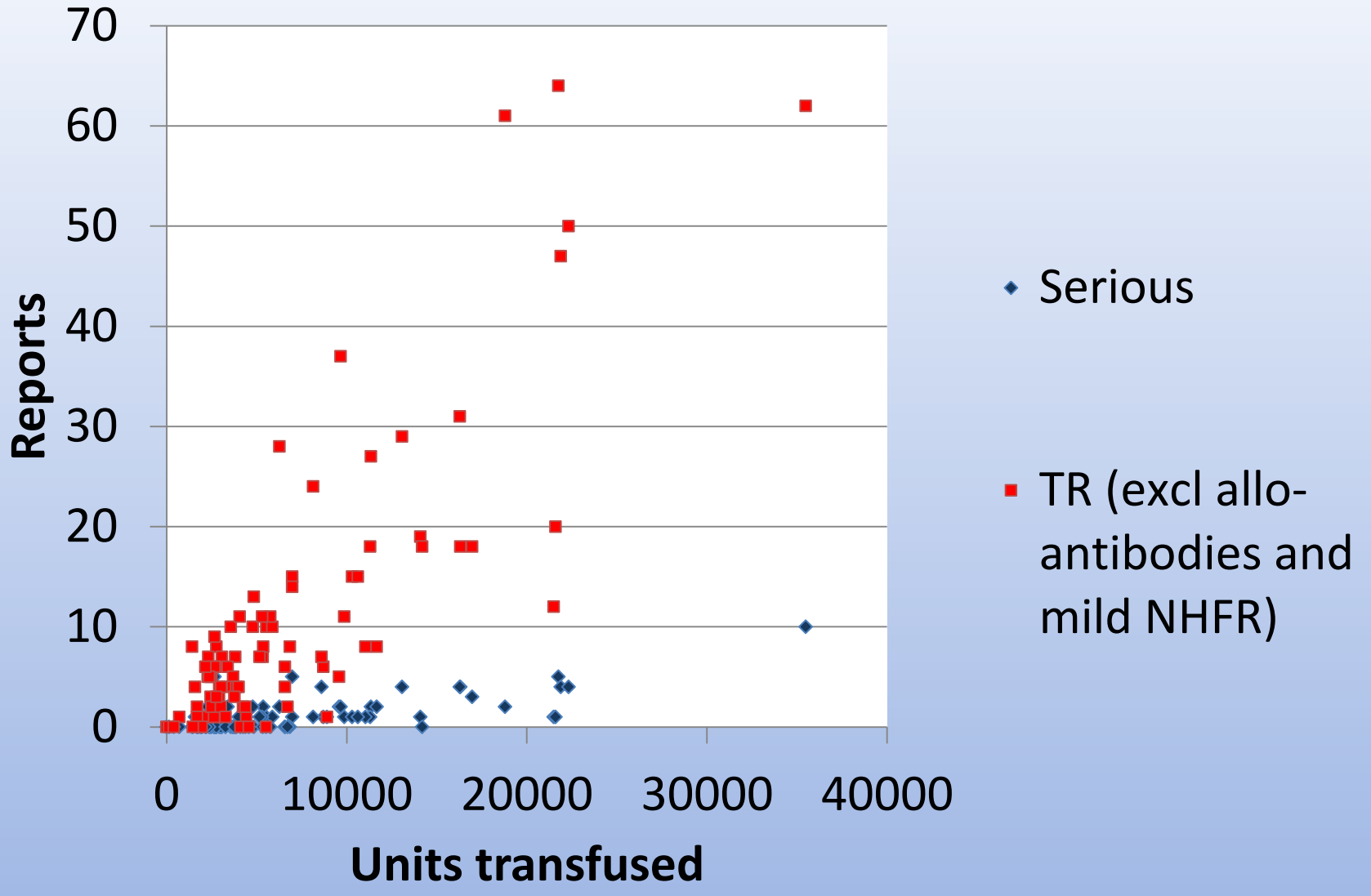
#independent events counted

International comparison

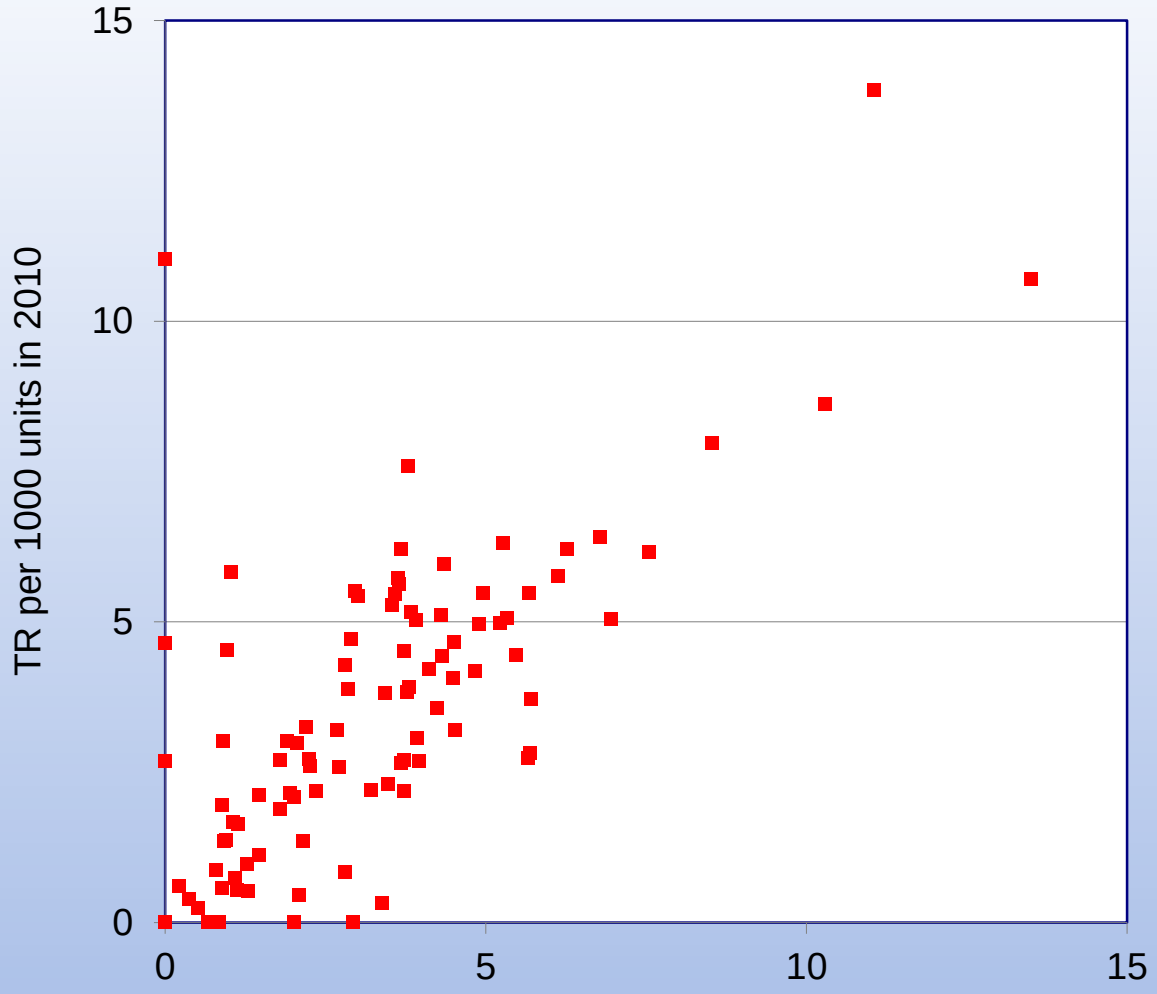
Country	Reports captured	per 1000 units			Status
		Total reports	IBCT	ABO-incompatible RBC	
France 2011	all	2.5	0.07[#]	0.001	Mandatory
UK 2011	serious	1.0*	0.08[$]	0.004	Voluntary[1]
Ireland 2008-9	serious	1.22	0.72[$]	0.005	Voluntary[1]
TRIP 2011	all	3.9	0.07	0.006	Voluntary[1]

#serious incidents with transfusion, grade 0 and grades 1-4
*including near miss
[$]not including handling & storage errors or inappropriate /unnecessary/delayed transfusions
[1]Originally voluntary, professionally mandated; later serious reactions/events subject to mandatory reporting

Variation in rate of reports per 1000 units



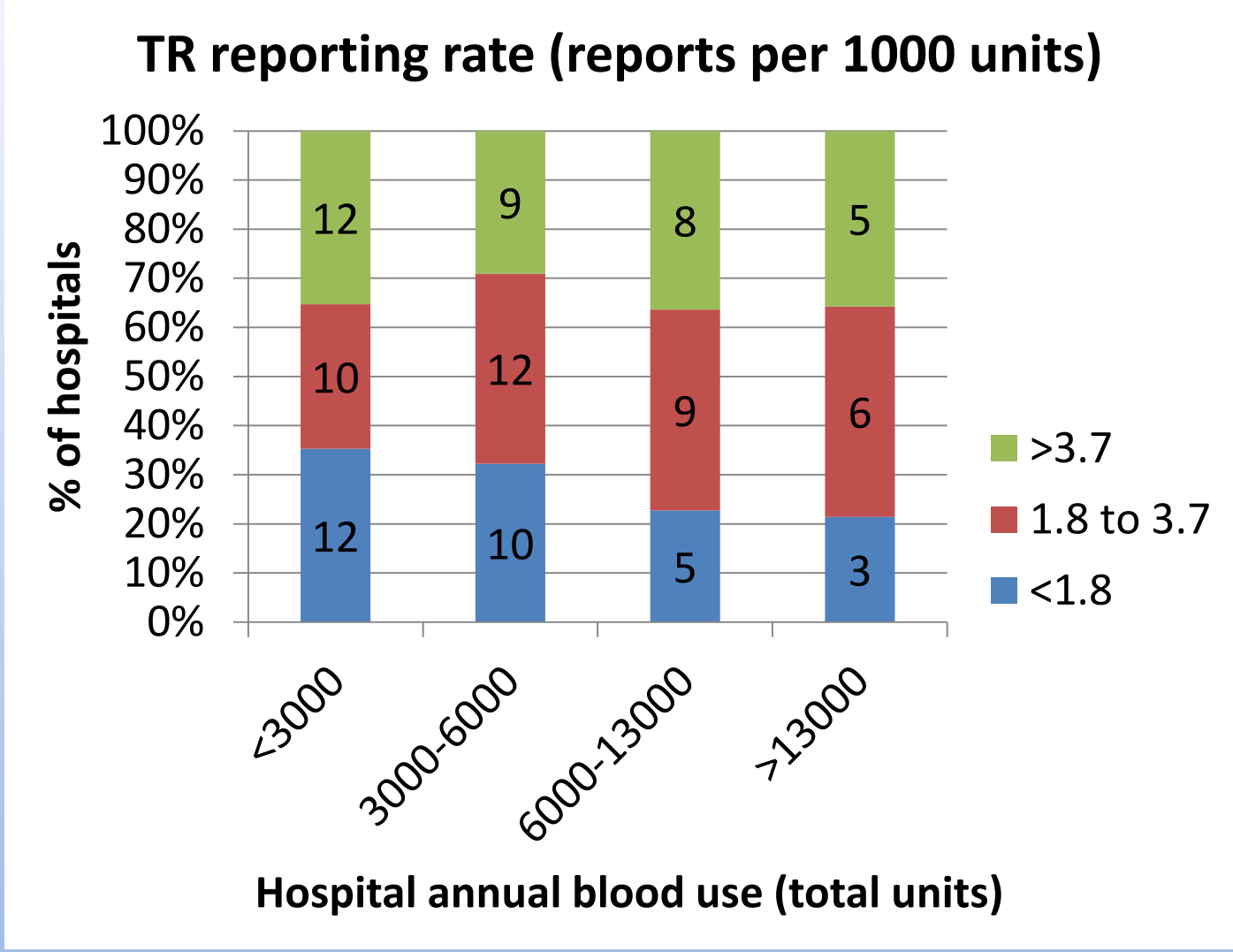
Consistency from year to year



Consistency from year to year:
Linear regression of rate in 2010 with 2009, 2006-8 and blood use level: $R^2 = 0.55$ ($p<0.001$)

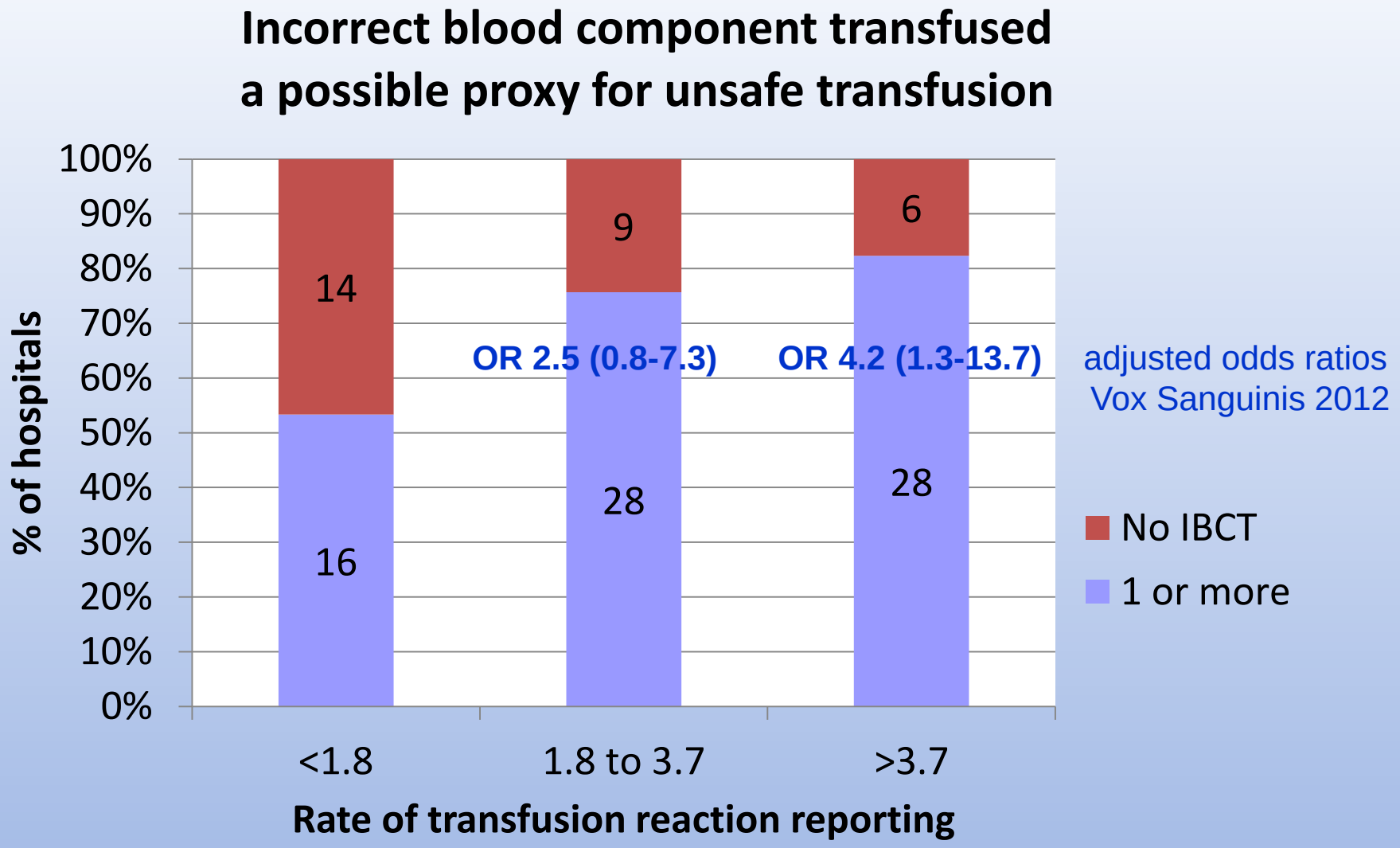
TR = transfusion reactions: definite, probable or possible, excluding new allo-antibodies and mild febrile reactions

Analysis of 2006-2010 data



TR = transfusion reactions: definite, probable or possible, excluding new allo-antibodies and mild febrile reactions

Are hospitals with more TR reports safer?



Conclusion: the data do not support that hospitals with a higher rate of transfusion reaction reports are safer

Prevention of transfusion reactions

Primary prevention

- product (blood component)
- hospital laboratory
- special product selection
- avoidance of unnecessary transfusion
- practice in clinical areas
- safety culture

Secondary prevention

- premedication
- special product selection

Tertiary prevention

- observation of patients under transfusion
- prompt response

TRIP
Hemo-en biovigilantie

Serious transfusion reactions (definite, probable, possible)	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**Total**
Other allergic	3	10	7	9	2	5			3	41
Anaphylactic	4	11	20	12	21	29	20	18	20	156
Mild NHFR ?	2	3	1		3	3	4	4	2	22
NHTR	4	11	10	20	17	21	15	7	8	115
TRALI	3	7	13	21	25	18	13	14	4	118
Other reaction	4	12	4	2	5	11	15	17	22	92
PTP									2	2

TRIP
Hemo-en biovigilantie

Serious transfusion reactions (definite, probable, possible)	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**Total**
Other allergic	3	10	7	9	2	5			3	41
Anaphylactic	4	11	20	12	21	29	20	18	20	156
Mild NHFR ?	2	3	1		3	3	4	4	2	22
NHTR	4	11	10	20	17	21	15	7	8	115
TRALI	3	7	13	21	25	18	13	14	4	118
Other reaction	4	12	4	2	5	11	15	17	22	92
PTP									2	2
Post-tf bacteremia/sepsis	2	1	5	3	3	3	1	4	3	25
Post-tf other infection									1	1
Post-tf viral infection PR?	1	1	1	2	2	1	0	0	1	9

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New allo-ab	1	3				3	2	1		10
Hemosiderosis				3	3	2		1	2	11
AHTR 50%	4	7	8	6	2	7	6	6	8	55
Delayed HTR	2	5	2	8	4	4	3	5	1	34
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Errors / incidents											
IBCT	**100%**	34	36	60	64	64	59	61	58	44	480
Other incident	**50%**	5	12	51	86	100	83	110	117	137	701

Preventability?

Perhaps 47% of total from this table

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National hemovigilance reporting

- Ensure strong participation
- Data validation
- Publish information

- Limitations
  - Observational system, variable reporting
  - No info about patients without reactions
  - Lack of patient outcome data

Yes and no

- We know more about what is going on
- Role of transfusion safety officers in hospitals
- International HV activity highlighted dangers of errors, bacterial contamination, TRALI
- TRIP data demonstrated effect of TRALI measure (male-only plasma)
- Reduction of ABO-incompatible RBC in UK and France
- Audit and sparing blood use *not* a result of hemovigilance reporting
- Bacteria: diversion pouch, improved cleansing, platelet bacteria screening before TRIP started
- No convincing reduction of errors (yet) in NL
- Is feedback and making recommendations enough to bring about improvements???

HV and other areas of vigilance: integration or fragmentation?

Where next?

Improve registration

- Patient's diagnosis, reason for Tf, clinical data
- Simplify for users to avoid reporting fatigue
- Service to hospitals: benchmarking data

Developments

- Collaborate with hospitals to monitor blood use indicators
- Strengthen links: Lareb, organ vigilance (etc.)
- Link with other sources of data e.g. health insurance
- Collaborate to avoid duplication (e.g. PROTON 2)
- More active dissemination of results and lessons (including peer-reviewed publications)

Acknowledgements

Donors

All who work in the transfusion chain

TRIP board, experts, colleagues

TRIP contact people

Dank aan Cathy Osselton