Does a higher rate of reported transfusion reactions mean a hospital is safer?

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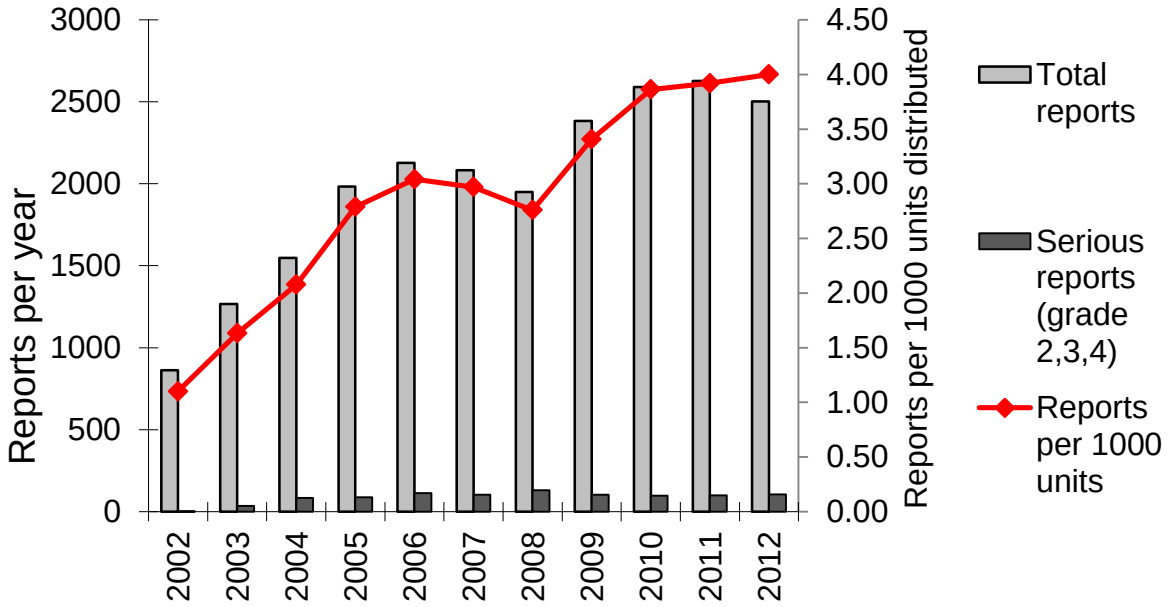
TRIP Hemovigilance and biovigilance office

Outline

- Hemovigilance reporting in The Netherlands
- Study: does a higher rate of reported transfusion reactions mean that a hospital is safer?
- Achieving safety improvement:
  - SHOT
  - France
  - Within-hospital learning?
- What are the ingredients for avoiding errors? How can we bring about improvement?

After ten years…



- Still counting, no apparent improvement: no reduction in numbers of reports
- Is there a parameter which could indicate safety of blood transfusion?

Variation in rate of reports per 1000 units

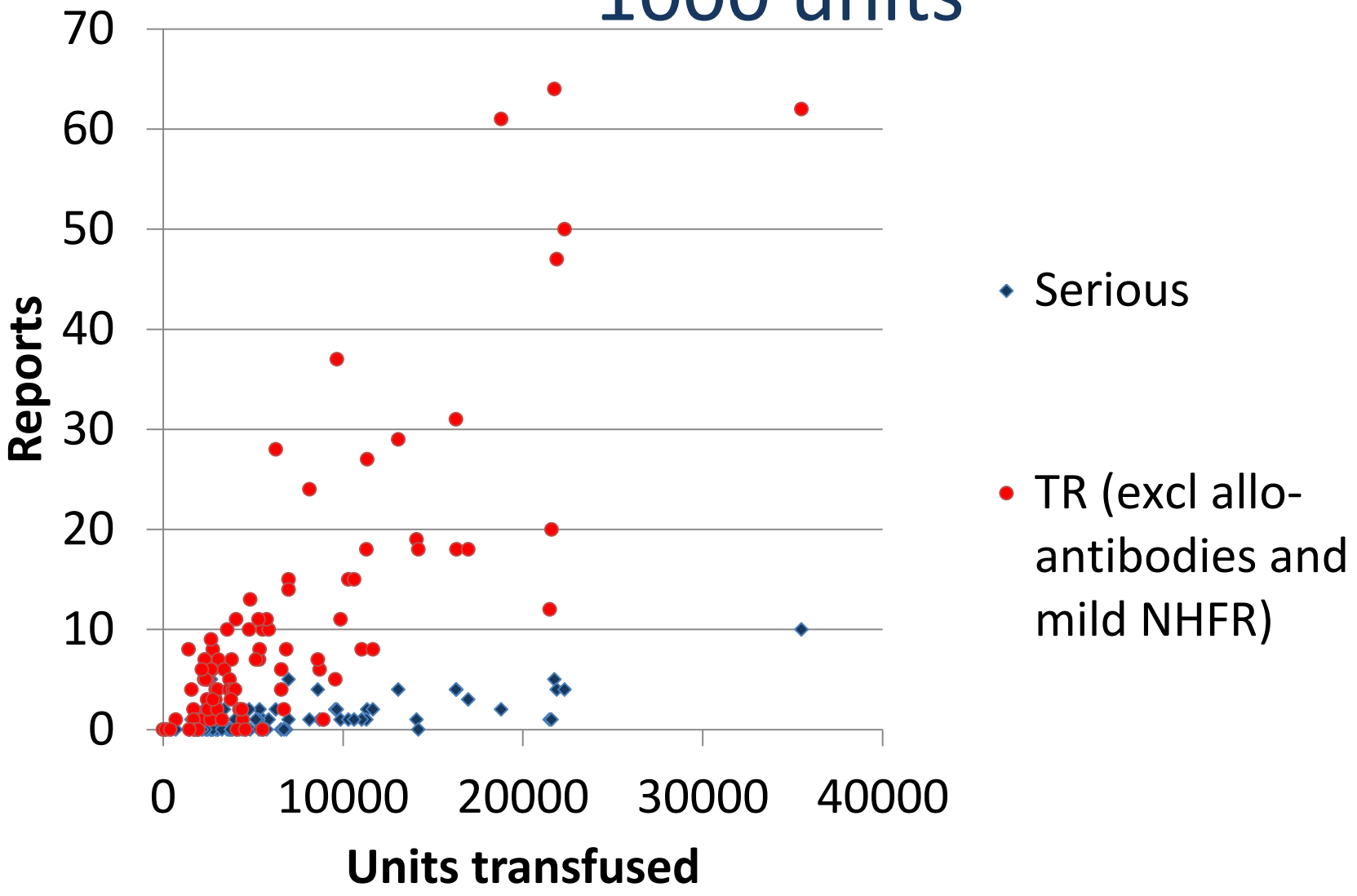


Figure 2.2–2.5
2010 participation

Total reports
per 1000 blood
components issued

Figure 2.2 Low usage organisations

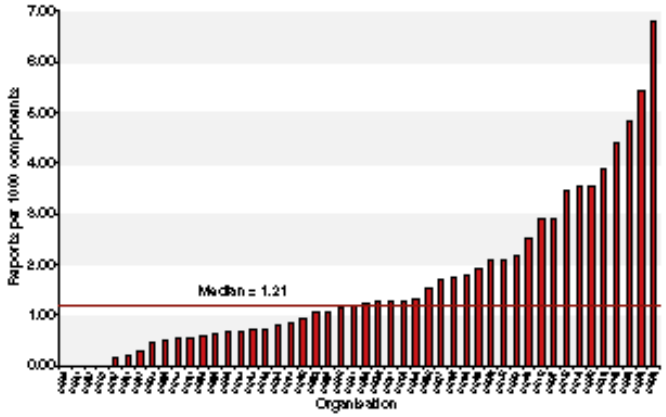


Figure 2.3 Medium usage organisations

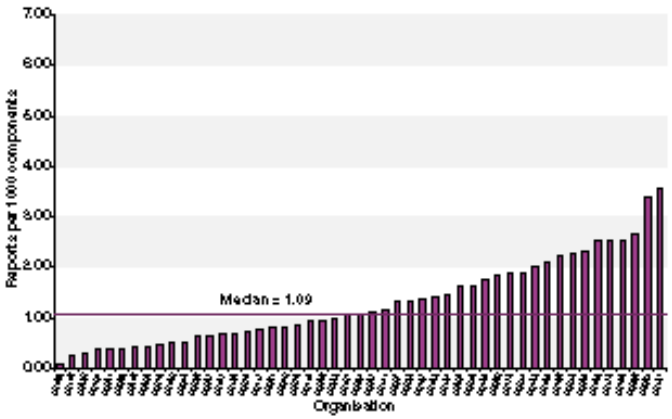


Figure 2.4 High usage organisations

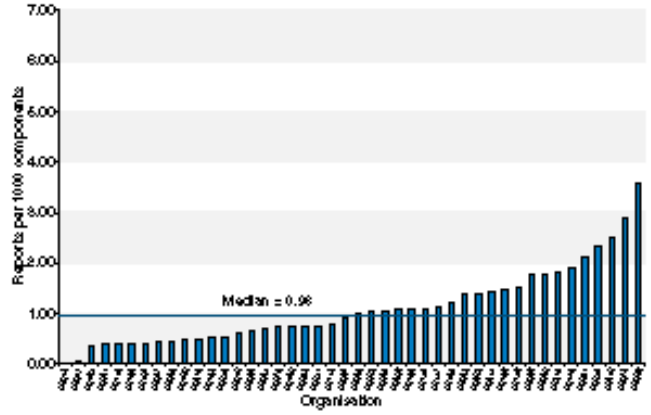
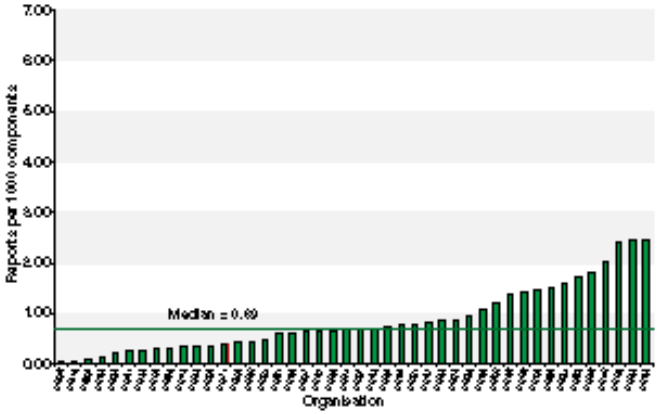
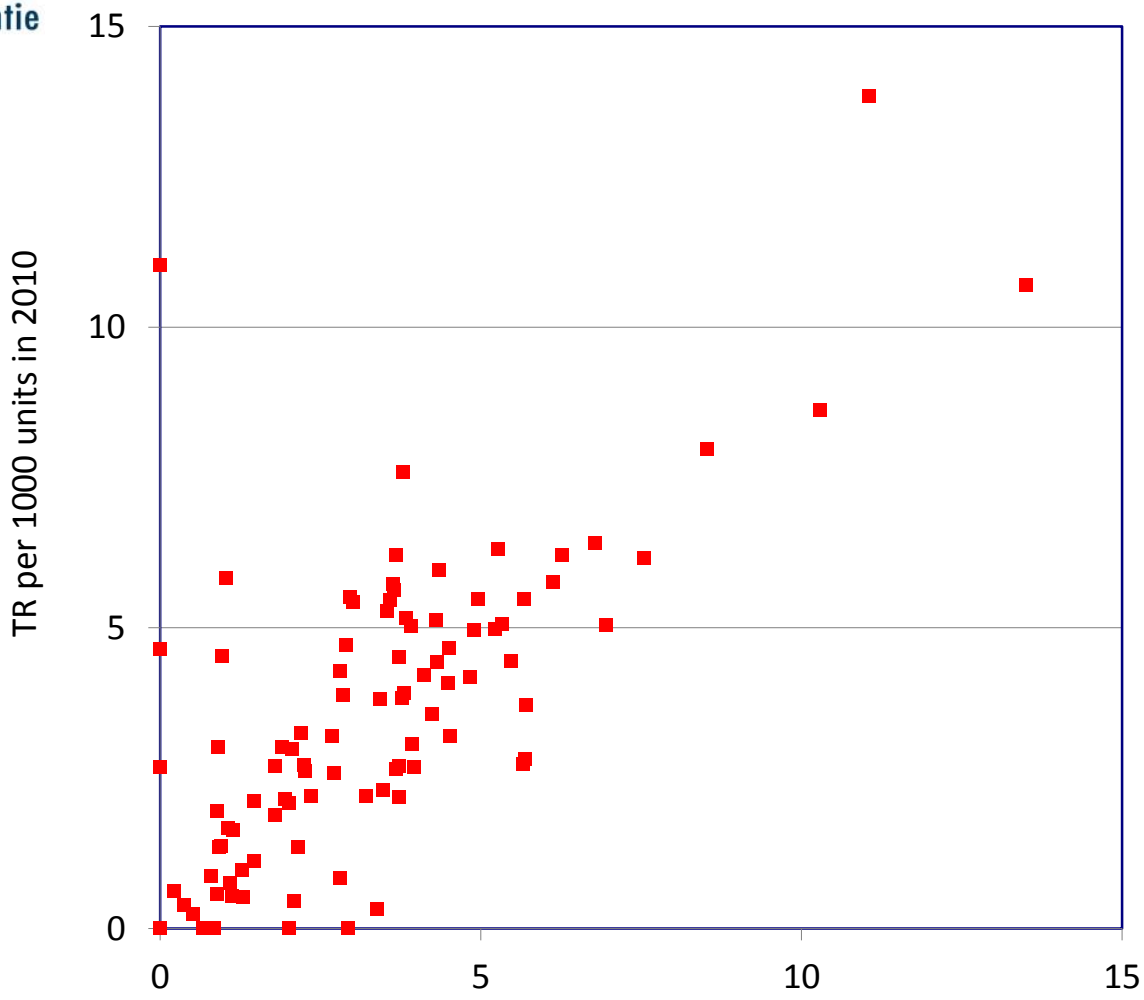


Figure 2.5 Very High usage organisations



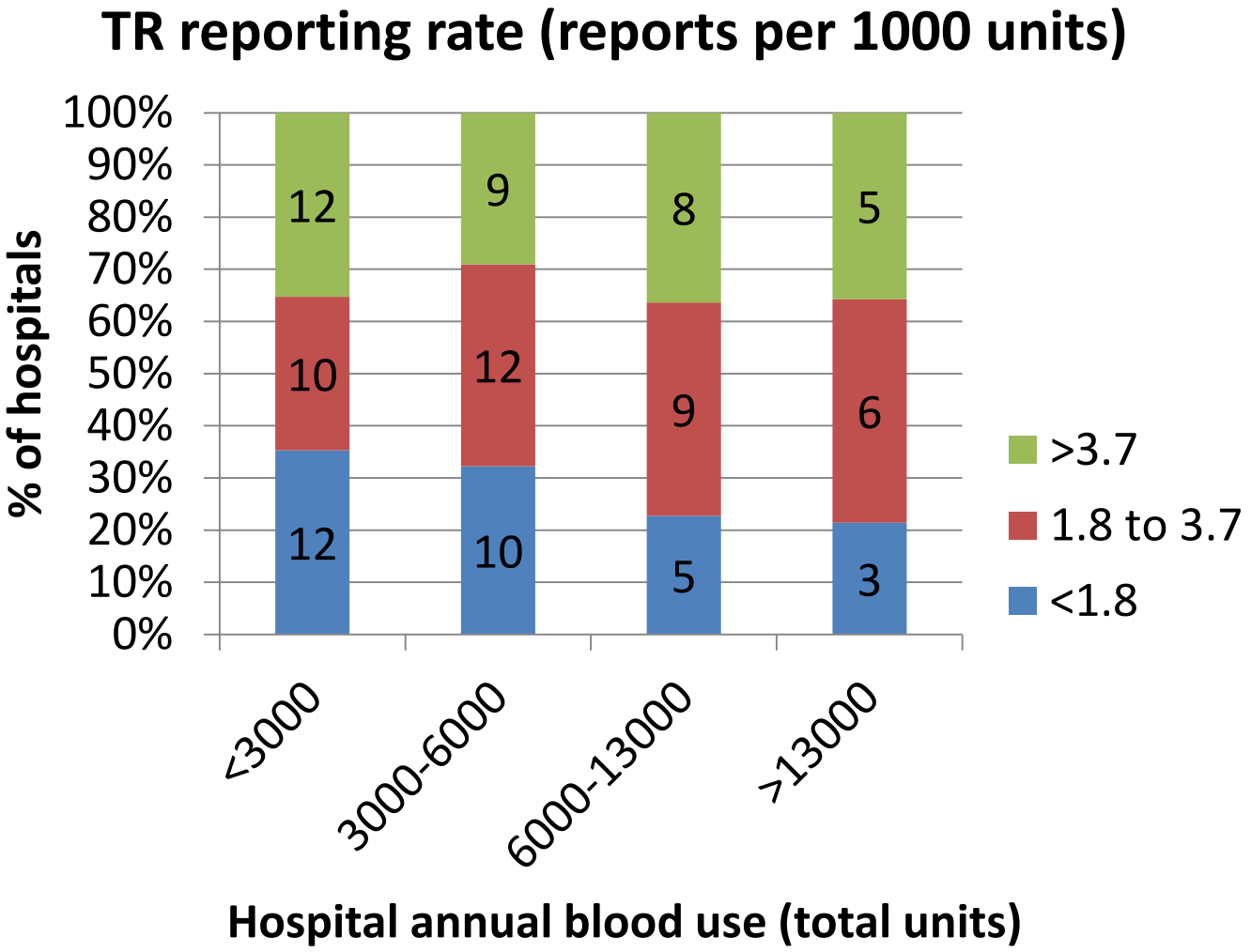
Consistency from year to year



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

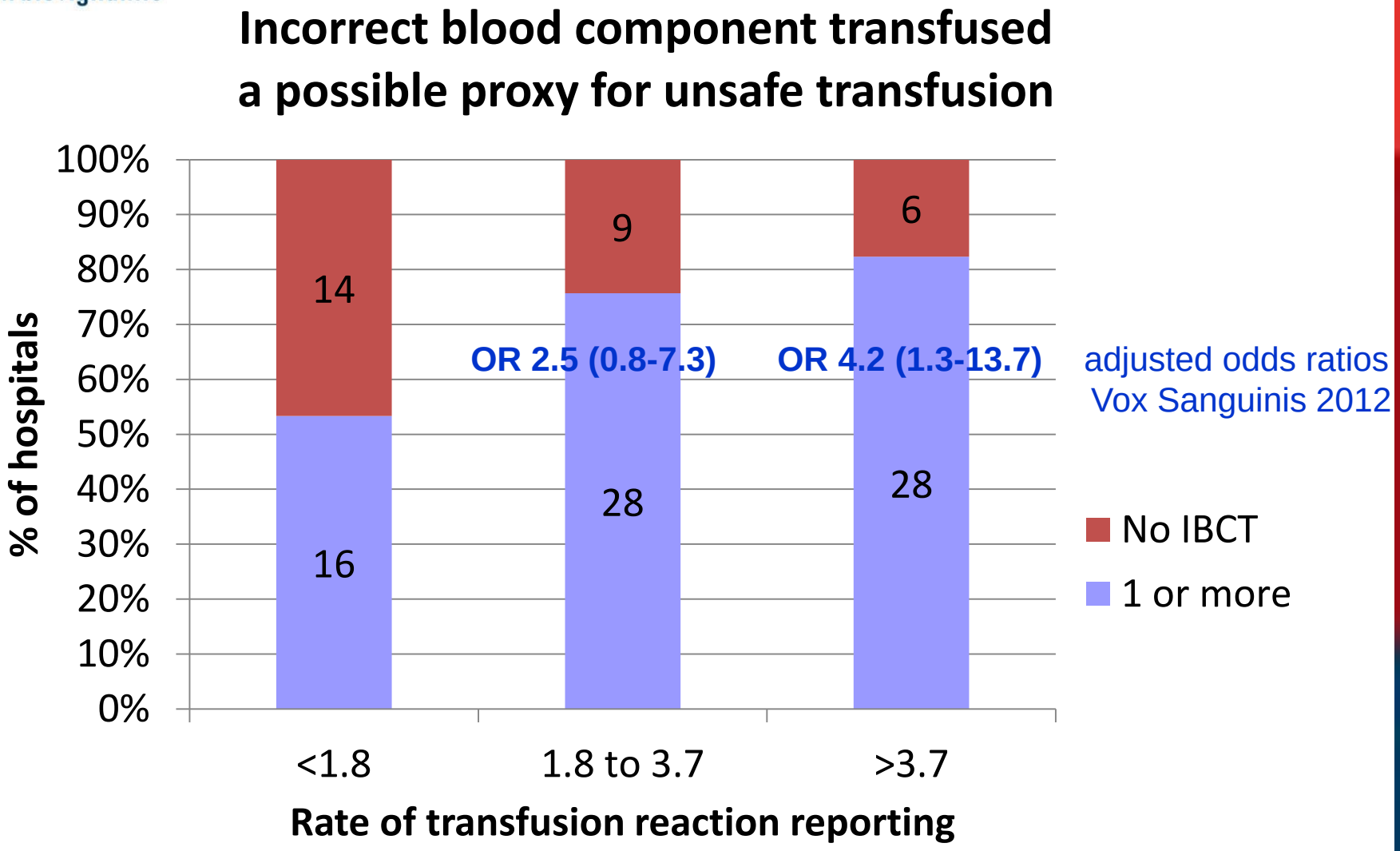
TR = transfusion reactions: definite, probable or possible, excluding new allo-antibodies and mild febrile reactions

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?



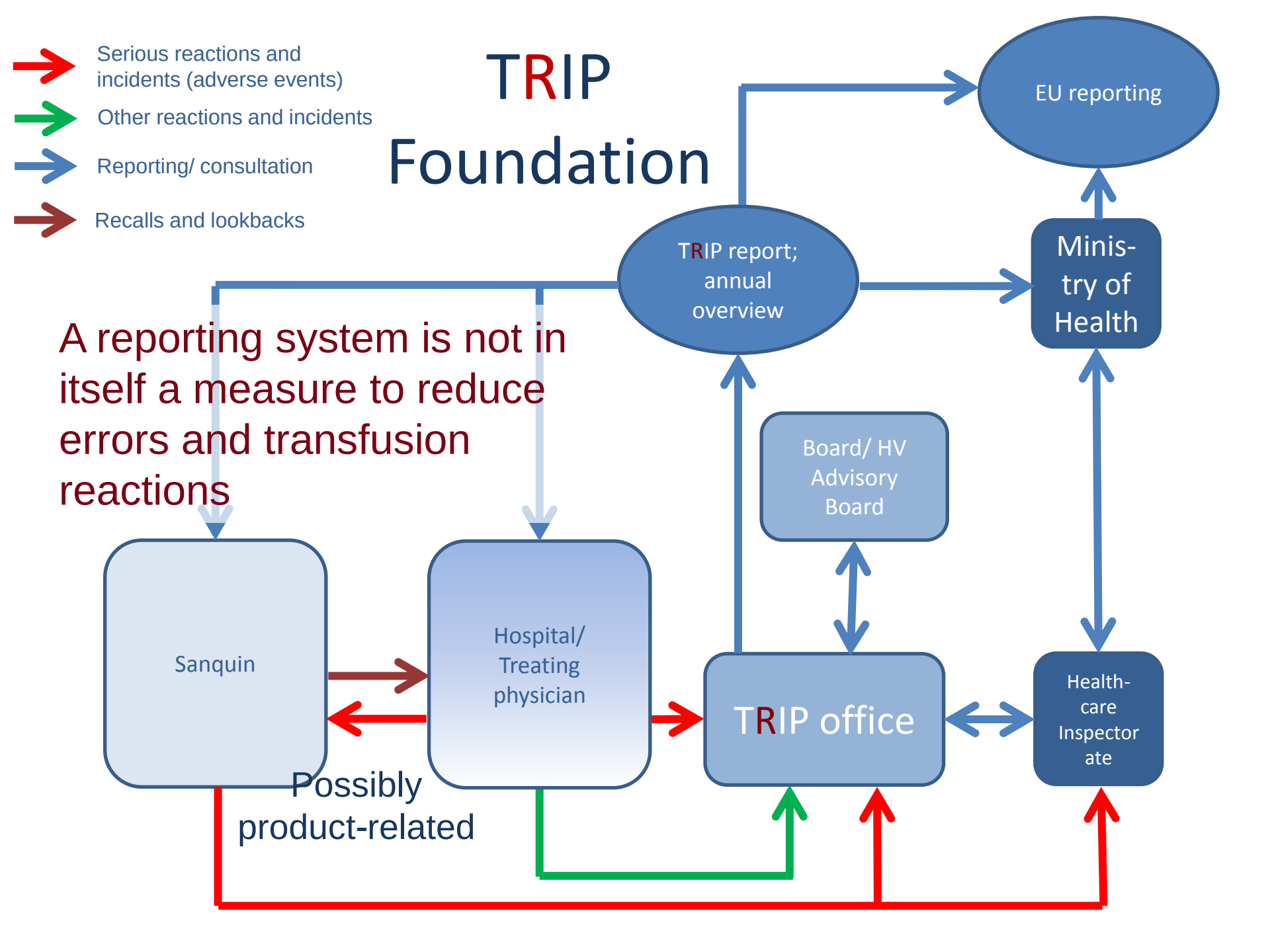
Conclusion: the data do not support that hospitals with a higher rate of transfusion reaction reports are safer

Hospital factors associated with higher likelihood of IBCT report

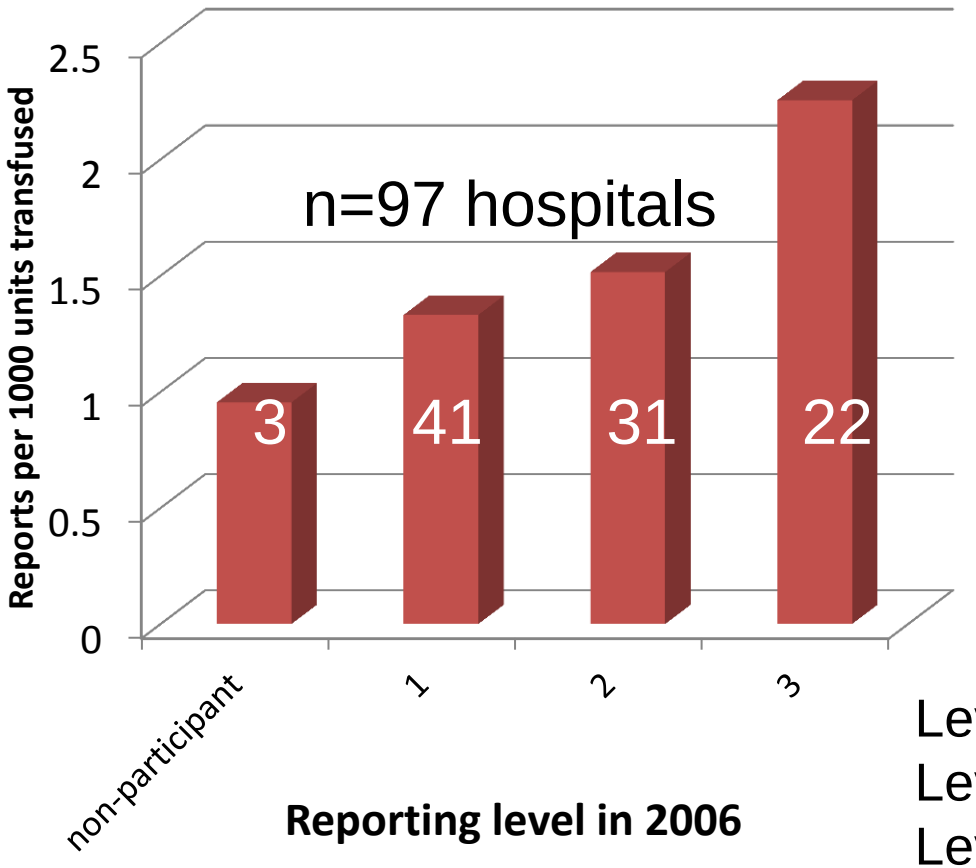
- Presence of transfusion safety officer
  - 1-4 years adjusted OR 2.8, 95% CI 0.6-13 vs no TSO
  - All years adjusted OR 2.2, 95% CI 0.2-6.1 vs no TSO
- Hospital also reported near miss or other incident
  - Near miss adjusted OR 14.2, 95% CI 3.0-66
  - Other incident OR 15.0, 95% CI 4.2-56
- Hospital also reported alloantibody formation or mild non-hemolytic febrile reactions (<2°C)

Conclusion:

Consistent with better surveillance and more complete reporting; *it cannot be excluded* that hospitals with higher rates of transfusion reactions may have more incorrect transfusions to report.


Serious reactions and incidents (adverse events)
Other reactions and incidents
Reporting/ consultation
Recalls and lookbacks
TRIP Foundation
EU reporting
TRIP report; annual overview
Minis-try of Health
A reporting system is not in itself a measure to reduce errors and transfusion reactions
Board/ HV Advisory Board
Sanquin
Hospital/ Treating physician
TRIP office
Health-care Inspector ate
Possibly product-related

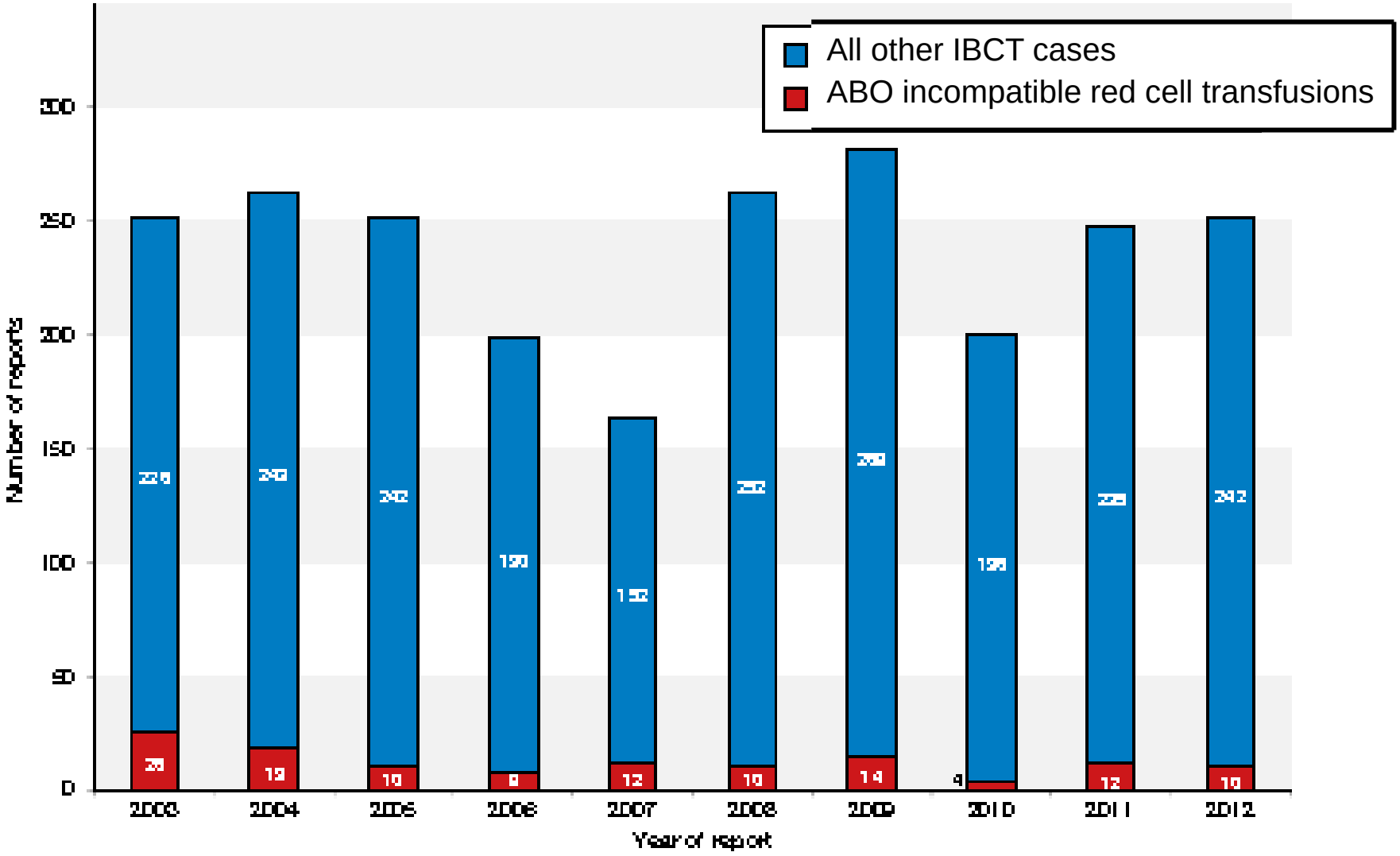
Consistency of reporting rate



Level 1 <1.8 TR/1000 u
Level 2 1.8-3.7 TR/1000 u
Level 3 >3.7 TR/1000 u

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

Data from SHOT



ABO incompatibility (France)

Reduction of ABO incompatible RBC transfusions

France	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
RBC	20	14	13	7	12	9	9	10	9	6	8	3	4
Plasma	5	4	1	0	1	0	0	0	0	0	0	2	0
Platelets	3	2	7	5	4	5	3	4	4	5	6	4	8

‘Contrôle ultime’ of ABO compatibility at bedside (since 1985); ministerial circular in 2003 stressed importance of identification of patient/unit

Incident reports to TRIP

Incidents	2008	2009	2010	2011	2012	Hospitals with reports (ever)
Incorrect blood component transfused	59	61	58	47	54	80
ABO-risk*	26	31	16	18	19	
ABO incompatible RBC transfusion	6	12	3	4	5	
Near miss	55	72	68	45	46	51
Other incident#	83	110	117	138	137	70

*TRIP assessment: risk to which the patient was exposed

#includes unnecessary transfusions and (SHOT term) “right blood right patient”

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

Johanna C. Wiersum-Osselton

Yes and no

Transfusion safety

Primary prevention

- Only transfuse if necessary
- Blood component
- Bloed transfusion laborato-ry: component selection
- Adhere to protocols, don't allow yourself to be distracted
- Patient safety culture

Secondary prevention

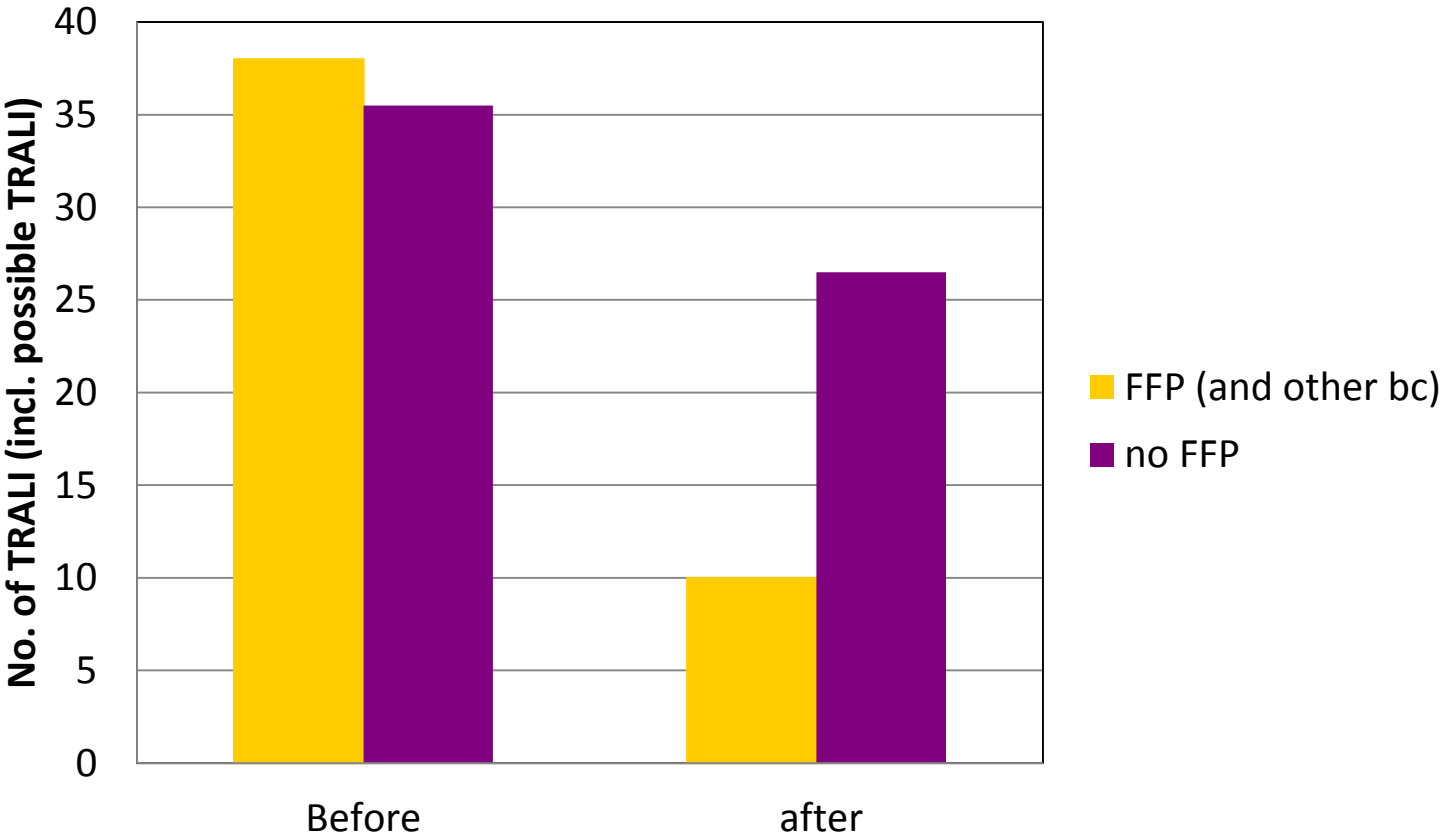
- Premedication (?)
- Component selection
- Speed of transfusion etc.

Tertiary prevention

- Monitor patient
- Respond appropriately

Training Professionals Management

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

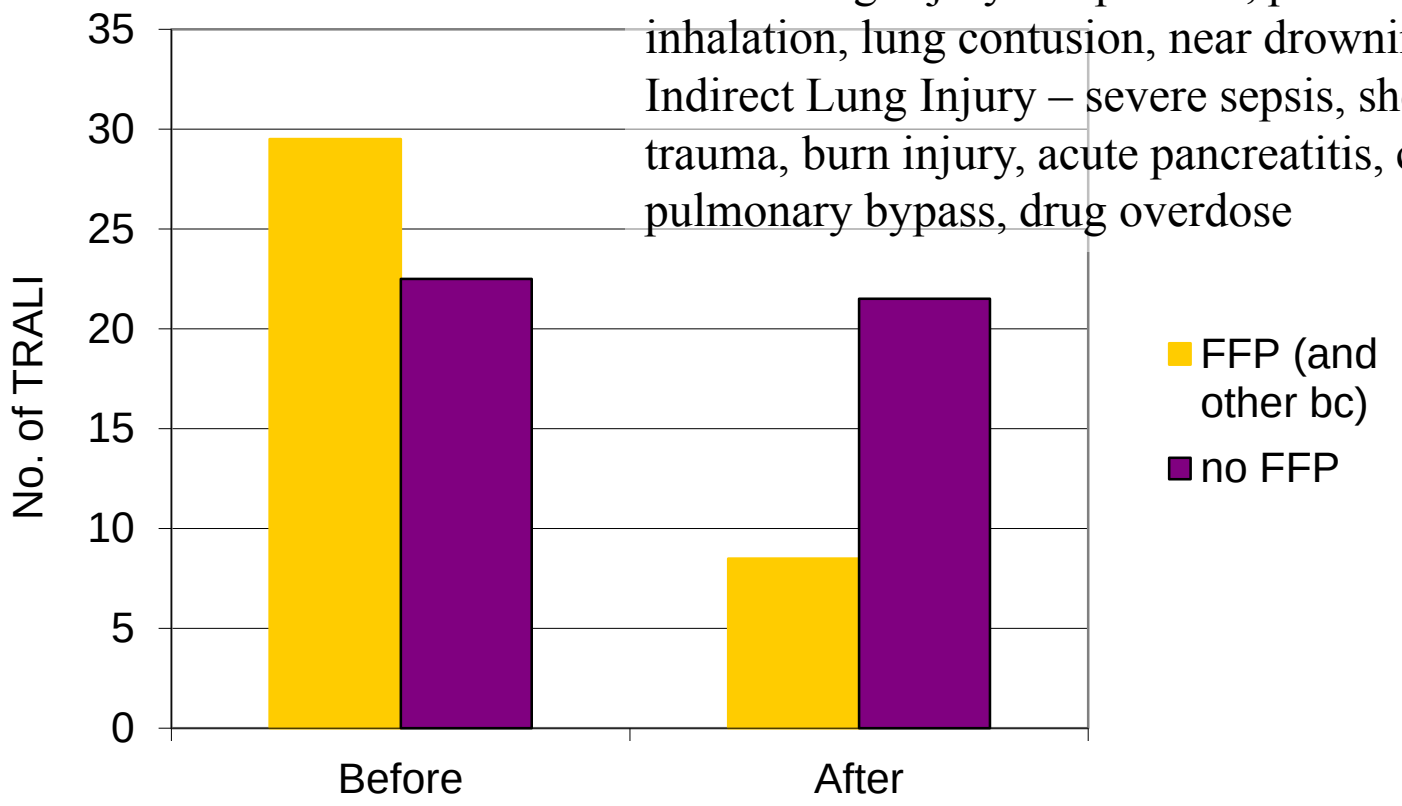


Prior to change
P.A.R. 0.33 (95% CI 0.09 – 0.51)

TRANSFUSION 2011;51:1278-1283.

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.

Hemovigilance data and bacterial contamination

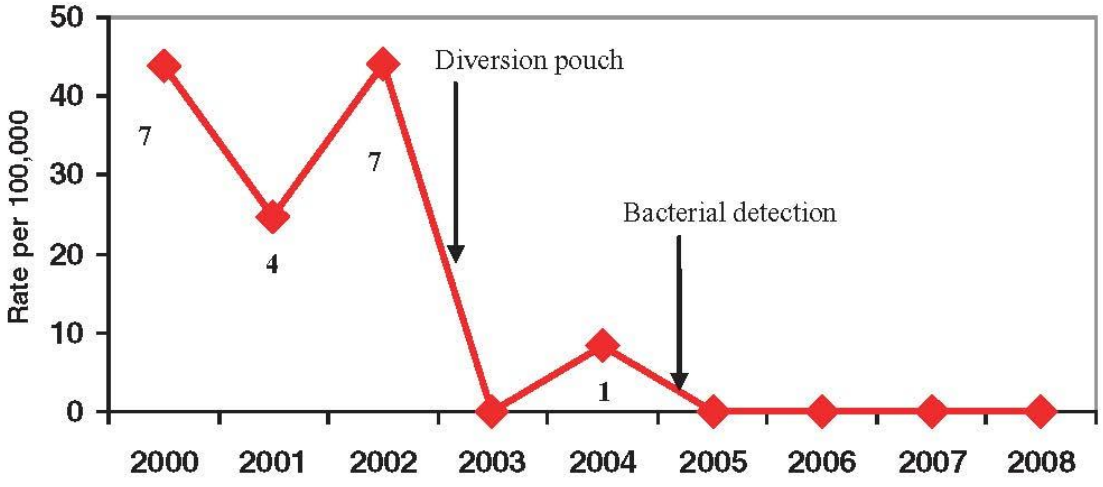


Fig. 1. Annual incidence of TTBIs per 100,000 pools of 5 units of WBDPs. The number of cases and time of implementation of preventive measures are shown on the graph.

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

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

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

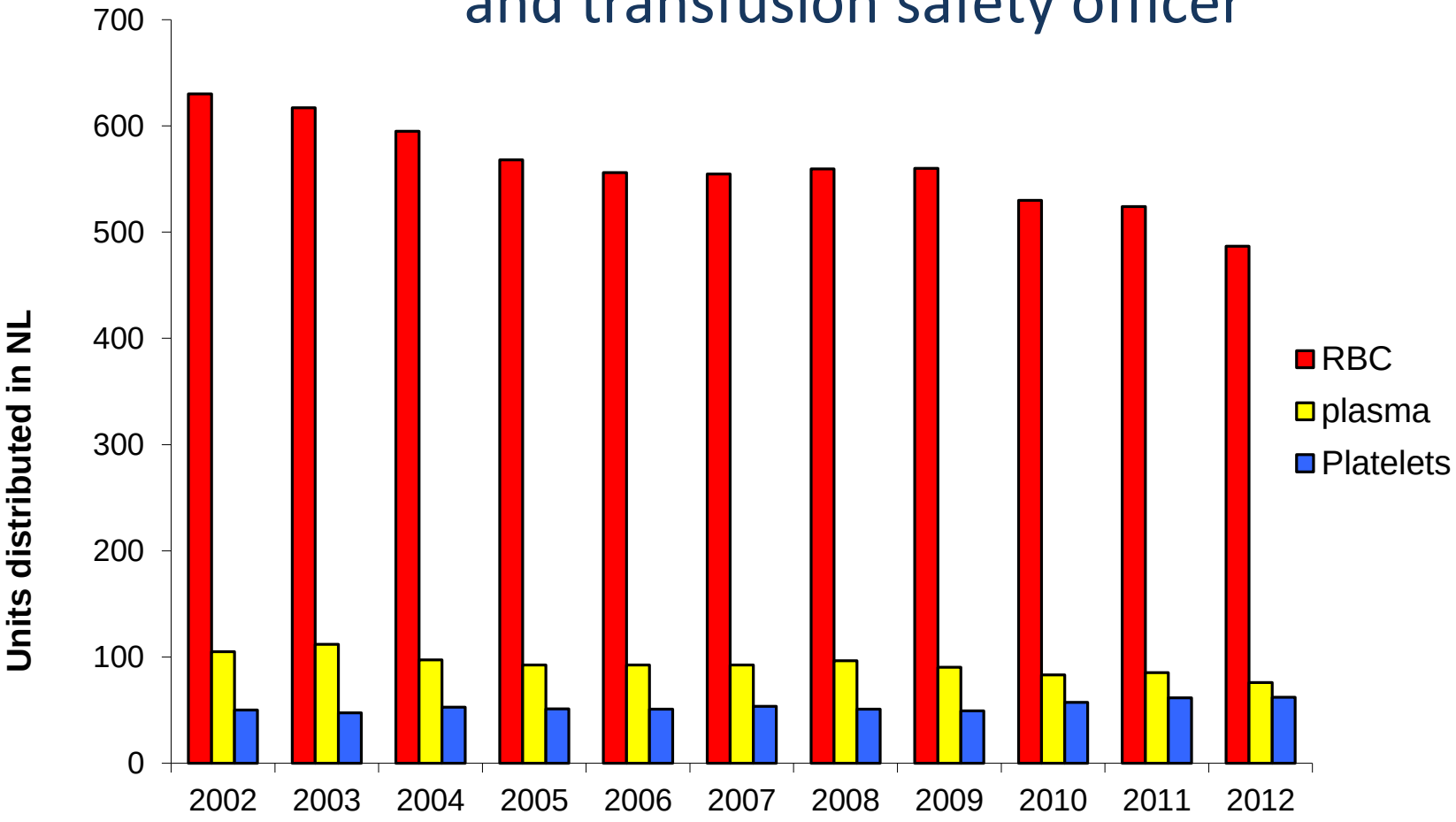
Transfusion reactions	2009-2011 cPCs		2011 & 2012 PI-PCs		PCs TRIP 2011
Units transfused	66,000		62,500		61665 distributed
	Reports	Rate per 1000	Reports	Rate per 1000	Rate per 1000
All definite / probable reports	223	3.4	160	2.5	2.2
Definite/ probable grade 3 reports	23	0.3	6	0.1	0.1
Septic transfusion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

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

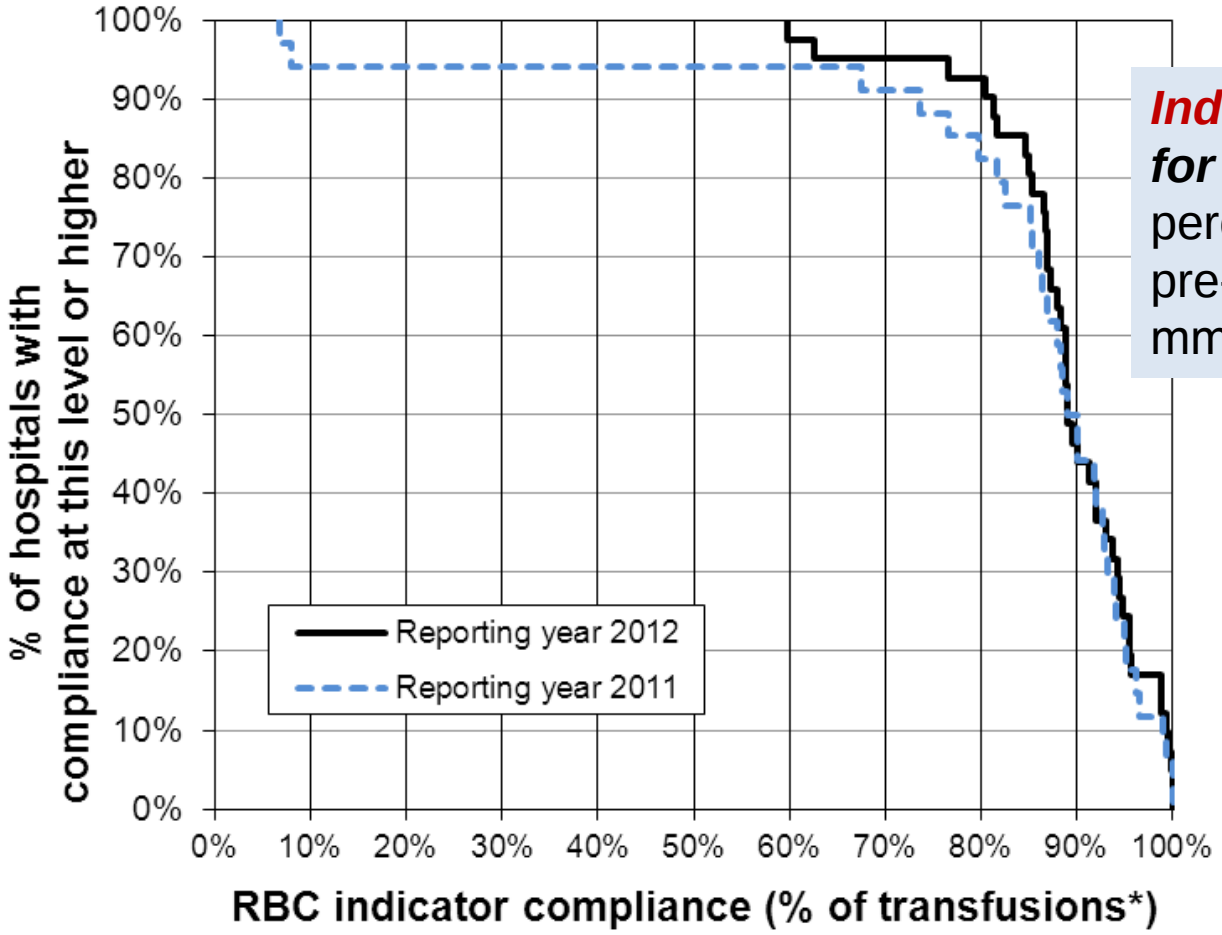
M. Ruesch et al, IHS Brussels 2013

Optimal blood use

Major role of blood transfusion committee and transfusion safety officer



Quality indicators for blood transfusion practice



Indicator 5 Indication setting for RBC transfusion: percentage of transfusions with pre-transfusion Hb level ≤ 6 mmol/l (≤ 9.6 g/dl)

Please also visit Poster no 2-22

Revised national transfusion guideline. 2011

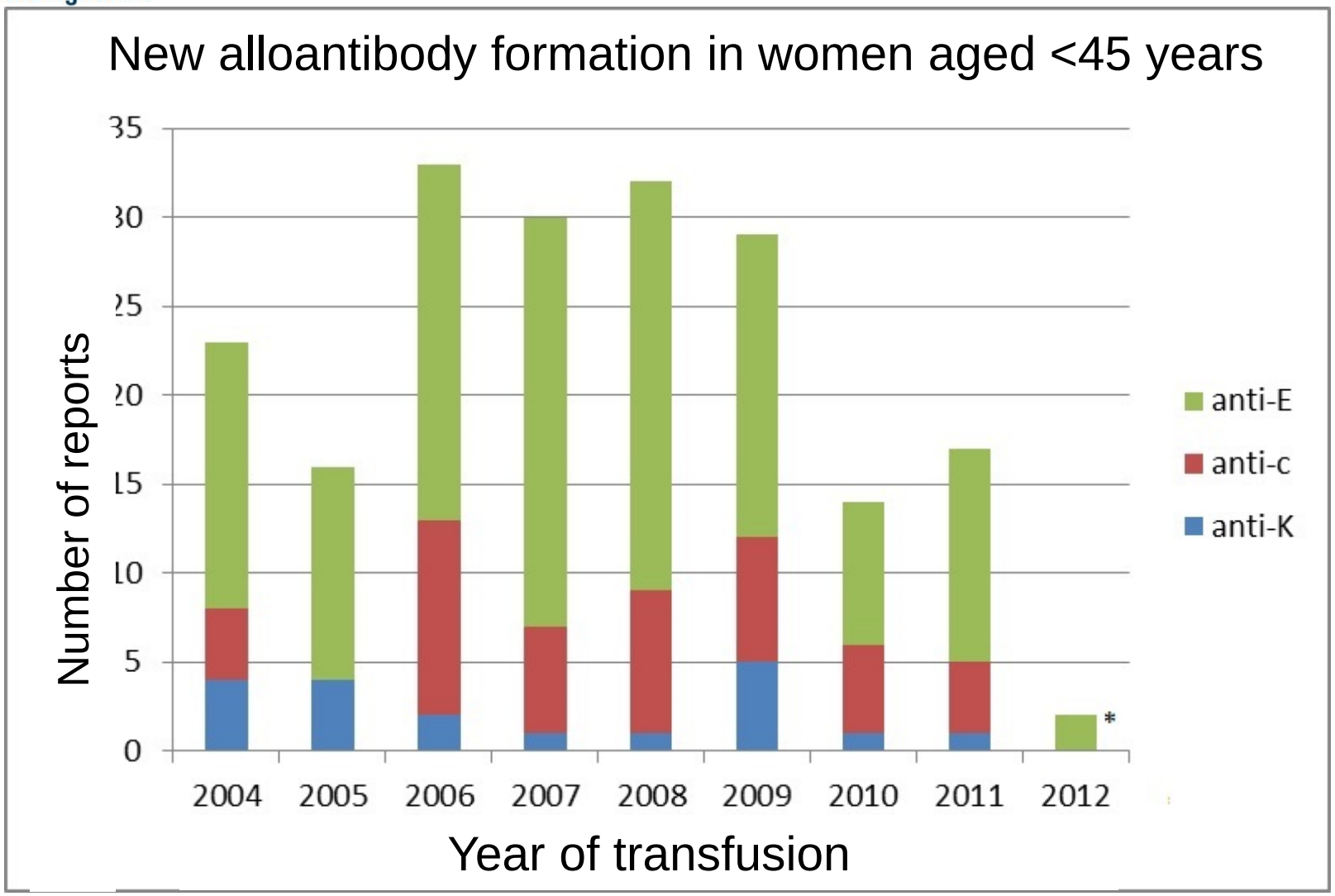
78% of hospitals voluntarily provided data:

transfusion committee 96%
TSO appointed 85%

		Indicator 2b TSO time allocation					
		≥ 8 hours/week		< 8 hours/week		Total	
Indicator 1b		2011	2012	2011	2012	2011	2012
Annual number of TC meetings	≥ 4	14%	23%	17%	13%	31%	35%
	< 4	36%	32%	33%	32%	69%	65%
	Total	50%	55%	50%	45%	100%	100%

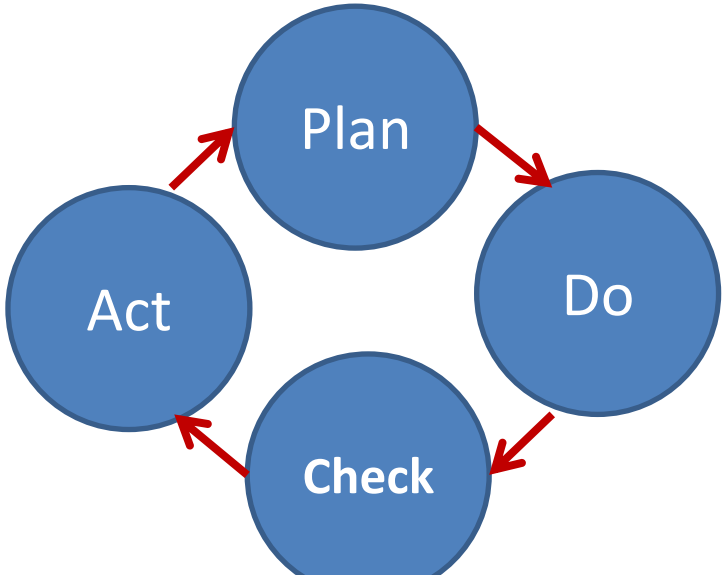
14% (2011) and 23% (2012) of responders complied both with the recommended minimum of four annual transfusion committee meetings and 8 hours' weekly employment of a transfusion safety officer.

Recommendation 2004: Kell negative or Kell compatible
2011: Rhesus c negative or compatible



Where next

- Limitations of HV data
  - Lack of info about uncomplicated transfusions!
  - Problems of underreporting, incomplete information
- Keep up good data collection (improve efficiency if possible)
- Results accessible for policymakers and professionals
- Apply lessons learned:
  - Implement measure
  - Evaluate
  - Tweak



Vigilance

In

Progress

IHN initiative

- representatives of HV systems with data
  - Data comparisons
  - Shared research projects
  - Evaluating measures
- Donor and recipient HV
- Kick-off meeting Friday 7th March
- If you are interested in participating or in receiving information: j.wiersum@tripnet.nl or ptomasulo@bloodsystems.org

Acknowledgements

- TRIP colleagues
- Hospital HV officers and TSOs in The Netherlands
- Colleagues from IHN member systems