TRIP Annual Report 2009

Trends in 7 years of hemovigilance reporting

Martin Schipperus

Director Dutch National Hemovigilance Office

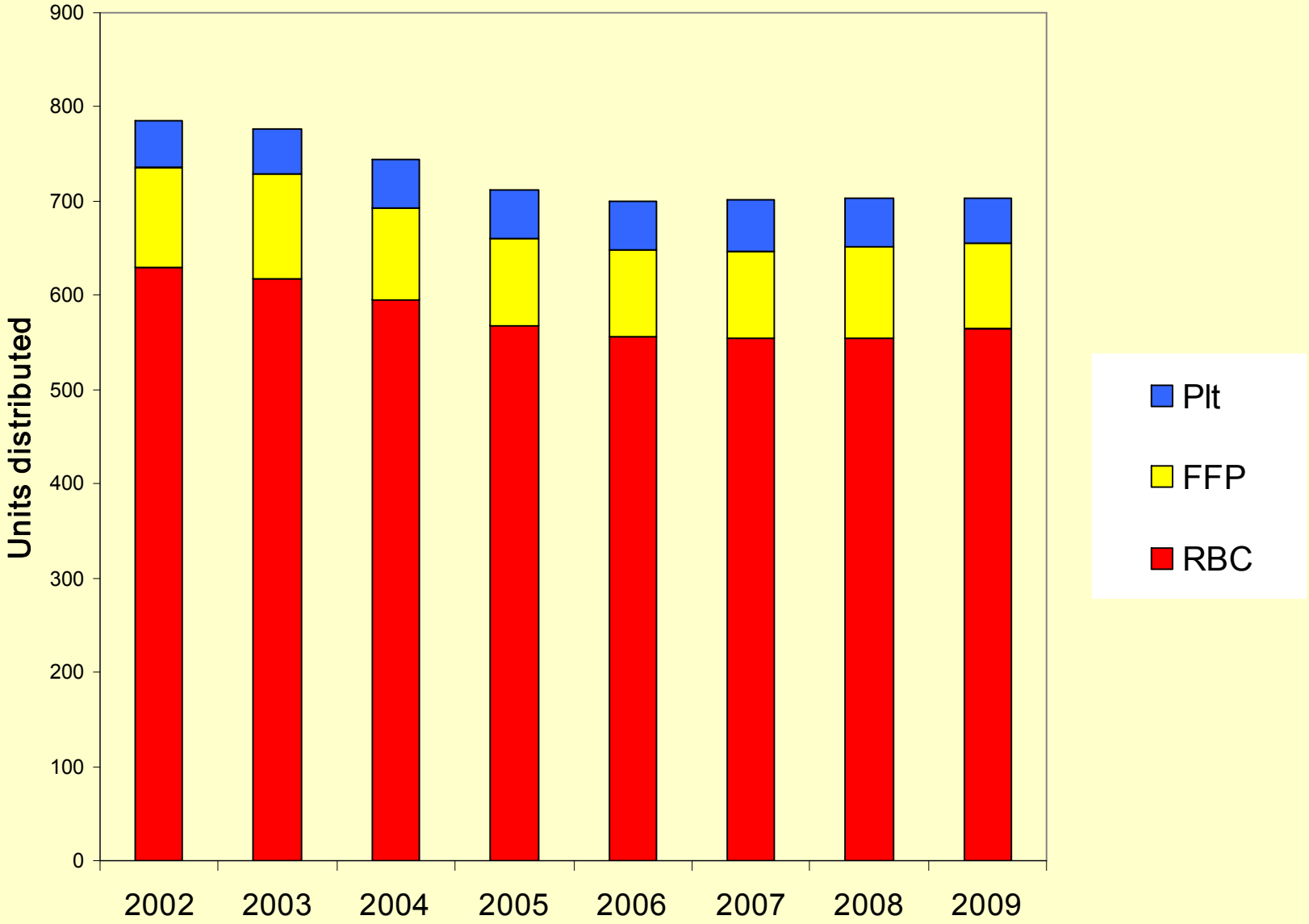
TRIP

TRIP annual report 2009
Hemovigilance

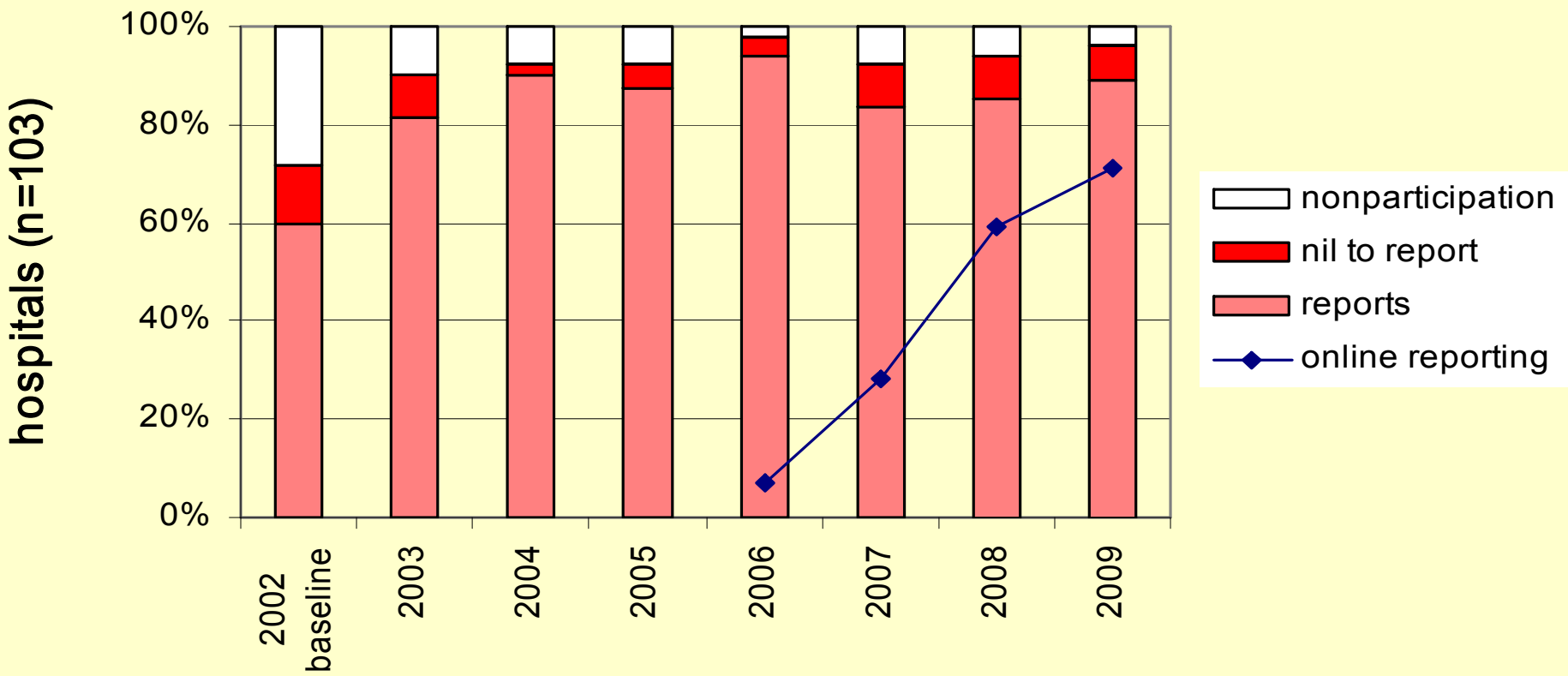
TRIP annual report 2009

- Participation
- Overview reports 2003 -2009
- Top 3 Transfusion Reactions
- Positive outcomes and goals for hemovigilance
- Incidents
- Concluding remarks

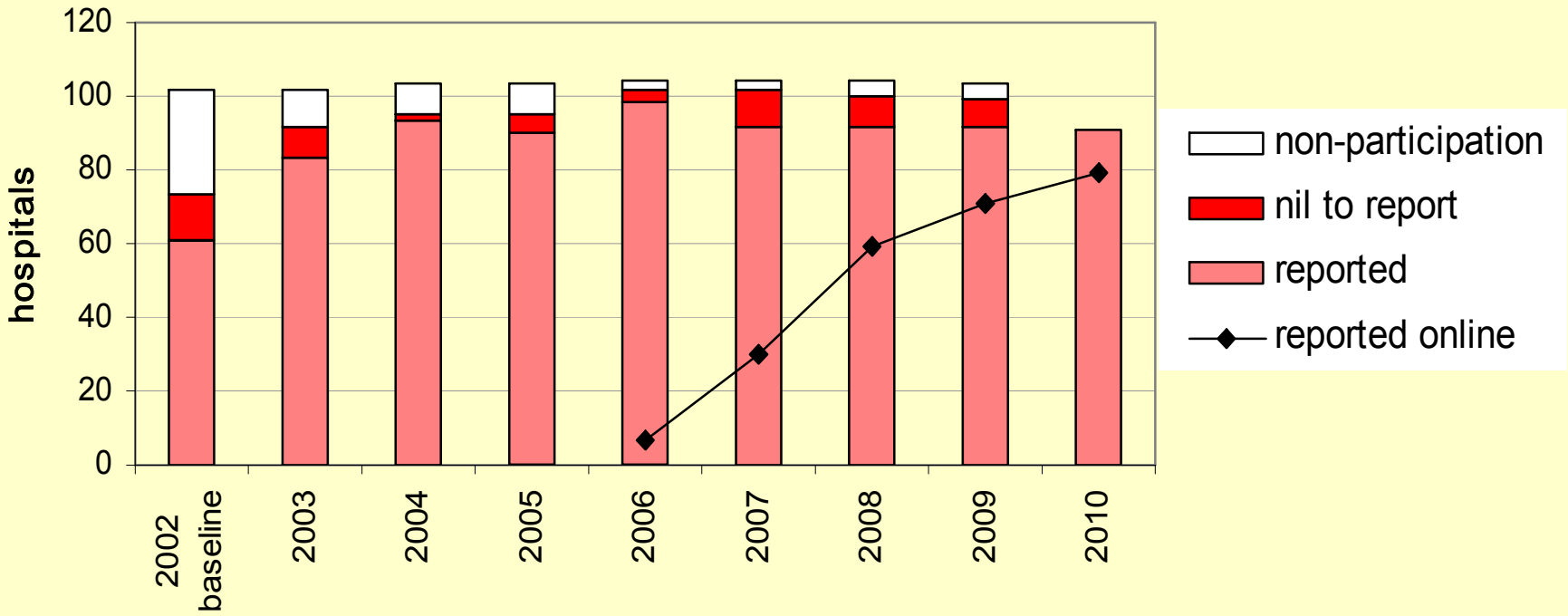
Annual blood use



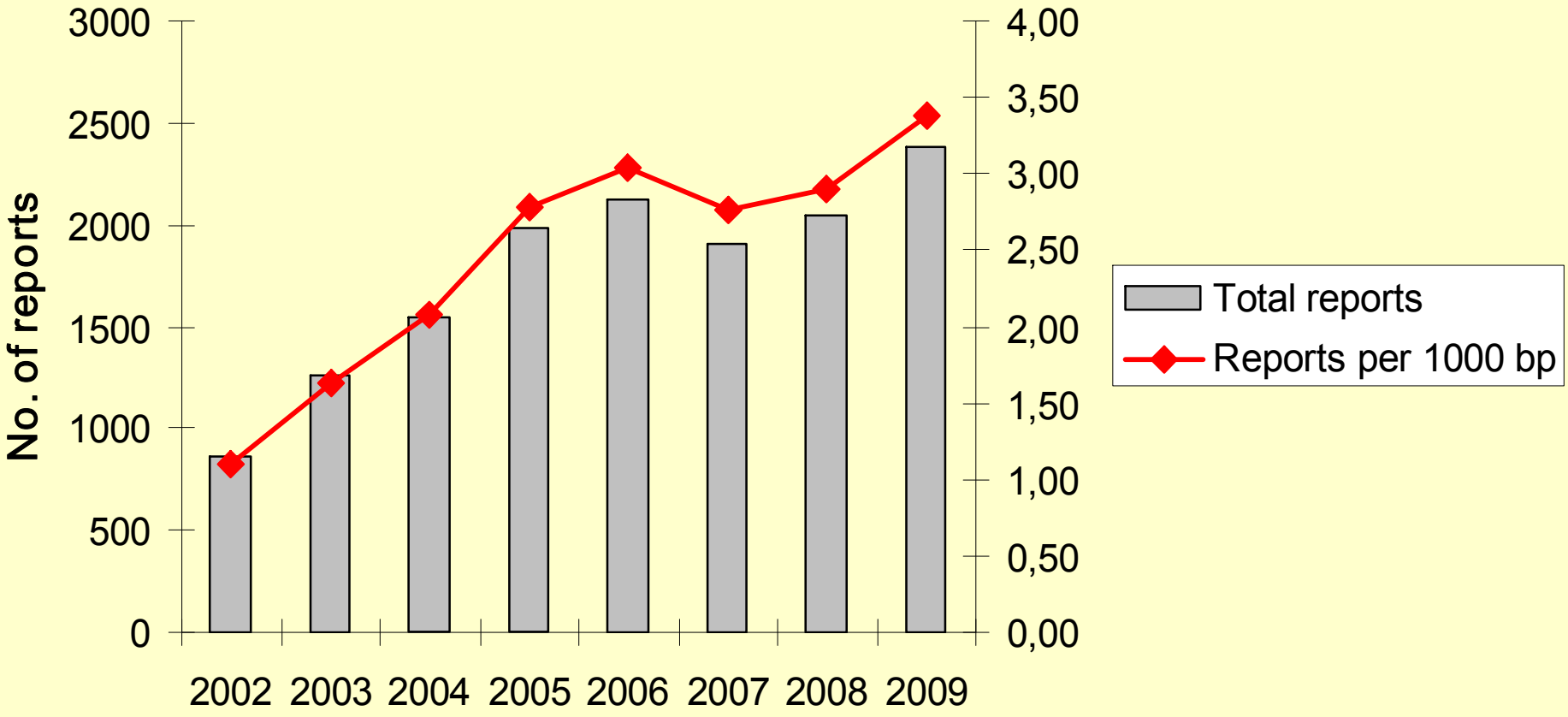
Participation



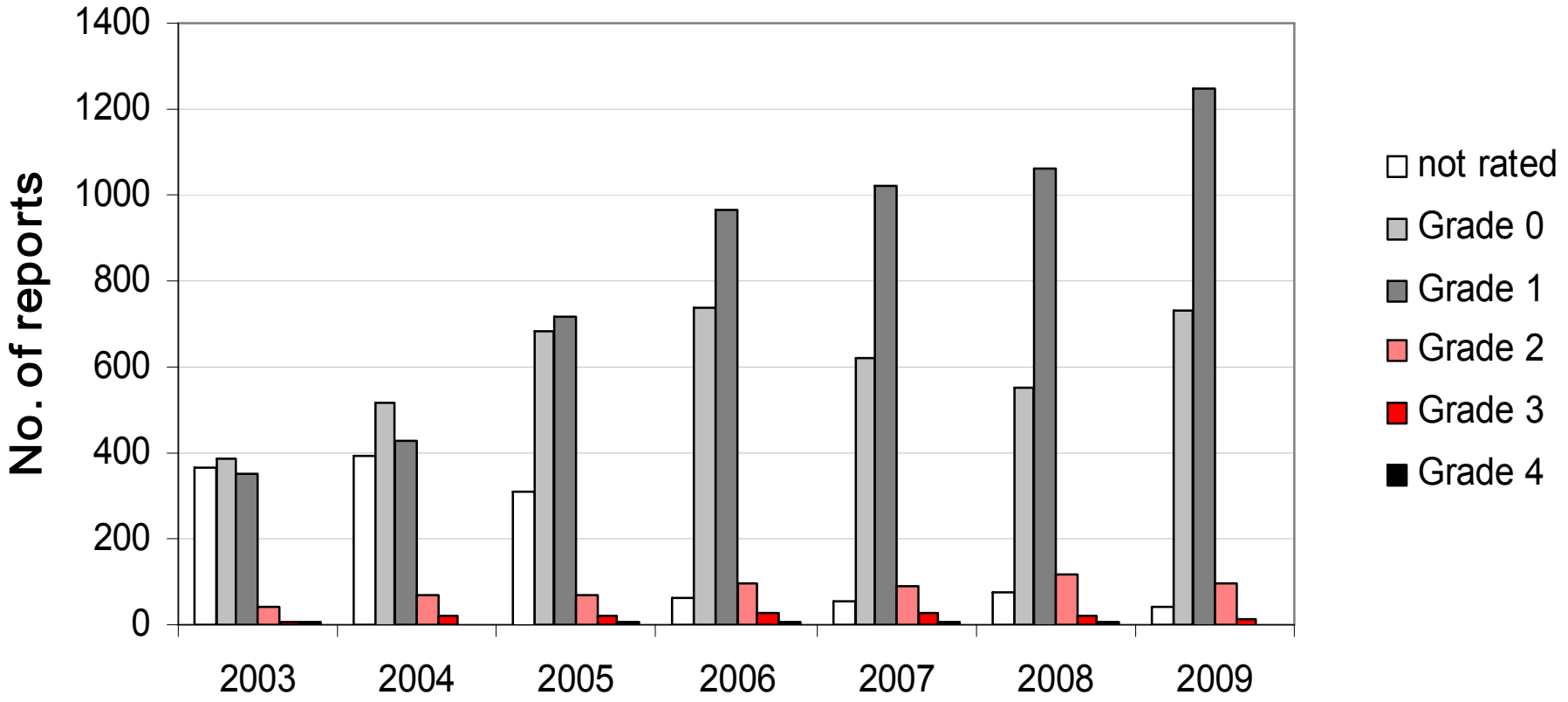
Participation, 2002-2010



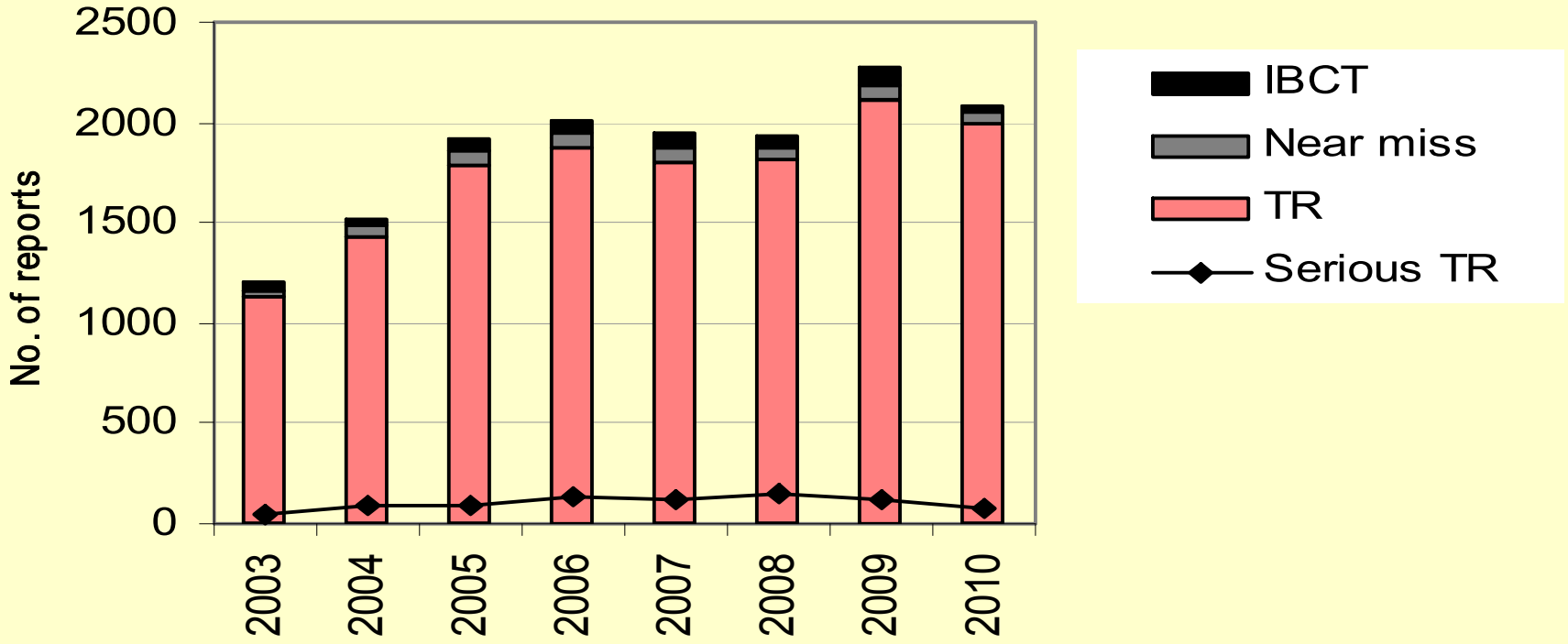
Number of reports 2002 - 2009



Severity


1400
1200
1000
800
600
400
200
0
No. of reports
2003
2004
2005
2006
2007
2008
2009
not rated
Grade 0
Grade 1
Grade 2
Grade 3
Grade 4

A first glimpse at 2010



(figures excluding 192 reports still in assessment phase; 21 serious)

TRANSFUSIE REACTIES IN PATIËNTEN

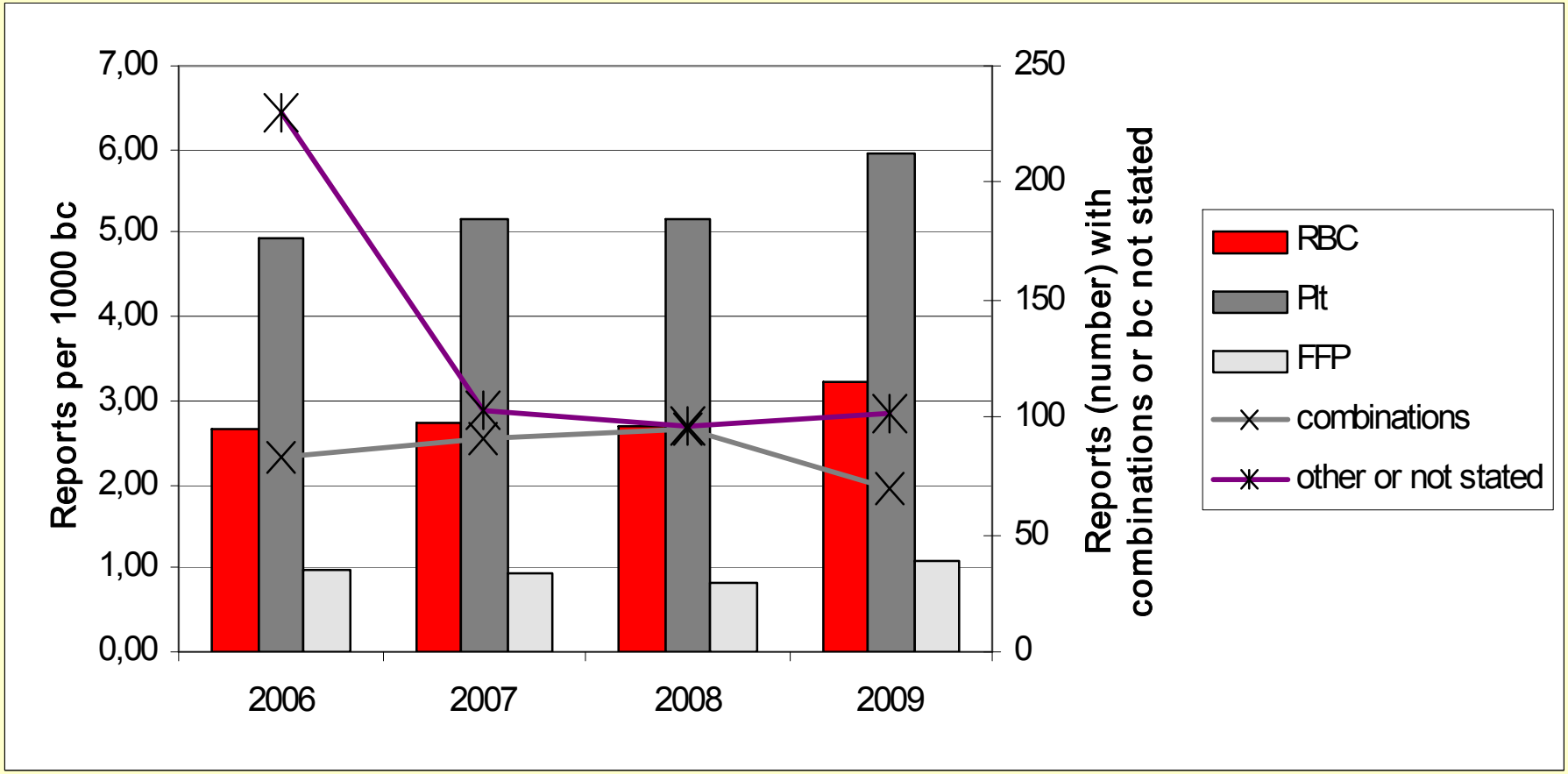
T R I P

Table 1 Transfusion reactions reported to TRIP, 2003–2009

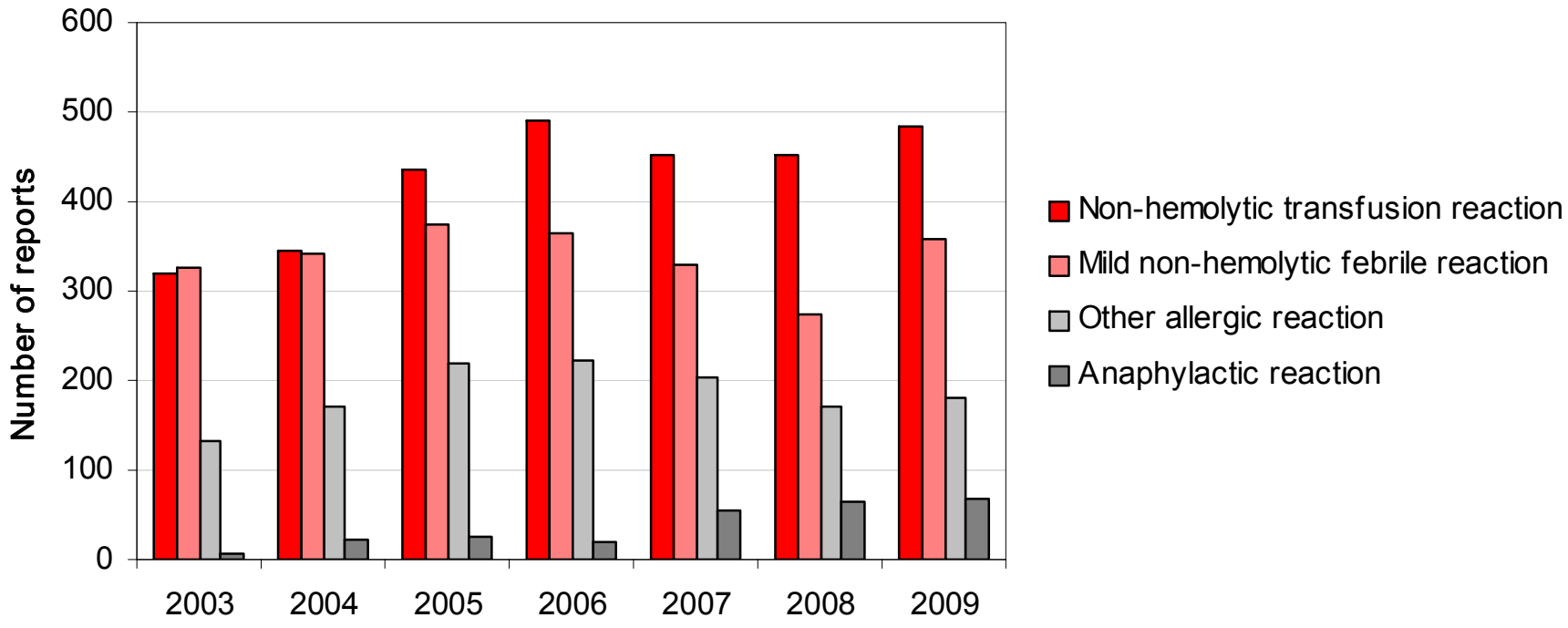
Reaction	2003	2004	2005	2006	2007	2008	2009	Grade 2 or higher #	No. hospitals with reports in 2009
NHTR	318	345	435	490	452	453	485	15	79
Mild febrile reaction	326	341	375	363	328	275	357	4	68
AHTR	8	14	9	19	11	18	18	6	16
DHTR	19	14	12	14	11	18	8	3	8
TRALI	7	9	17	25	31	21	12	12	10
Anaphylactic reaction	8	21	26	19	54	65	69	19	31
Other allergic reaction	132	171	219	222	202	171	180	0	48
Circulatory overload	7	6	27	34	31	39	41	14	22
Post-transfusion purpura	0	0	0	0	0	1	0	0	0
TA-GVHD	0	0	0	0	0	1	0	0	0
Hemosiderosis	0	0	3	5	3	5	2	0	1
New allo-antibody	244	428	571	607	601	607	753	2	60
Other reaction	54	64	67	61	55	101	132	15	45
Post-tf bacteremia / sepsis§	9	5	10	7	19	37	50	0	34
Post-tf viral infection	5	7	8	7	7	7	2	0	2
Total TR	**1137**	**1425**	**1779**	**1873**	**1805**	**1819**	**2109**	**90**	**92**
Total reports*	**1268**	**1547**	**1984**	**2130**	**2081**	**2052**	**2384**	**98 ***	**92**

imputability certain, probable or possible
§ up to and including 2007: bacterial contamination; see definitions on www.tripnet.nl
* Total transfusion reactions and incidents

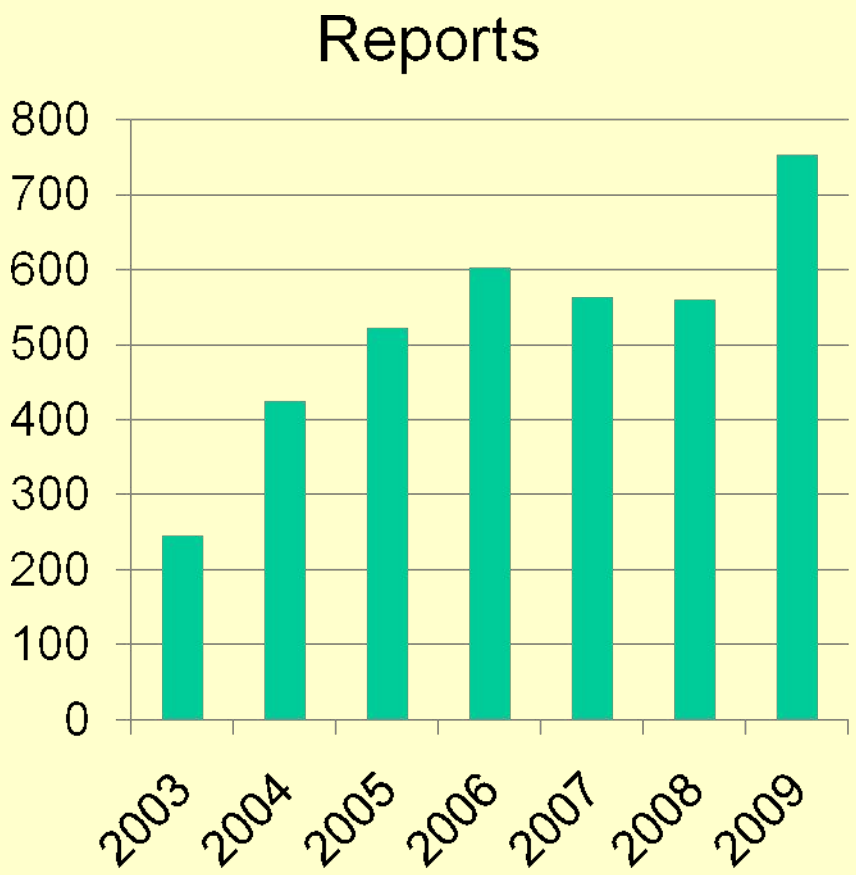
Number of reports per type of blood component, 2006 – 2009

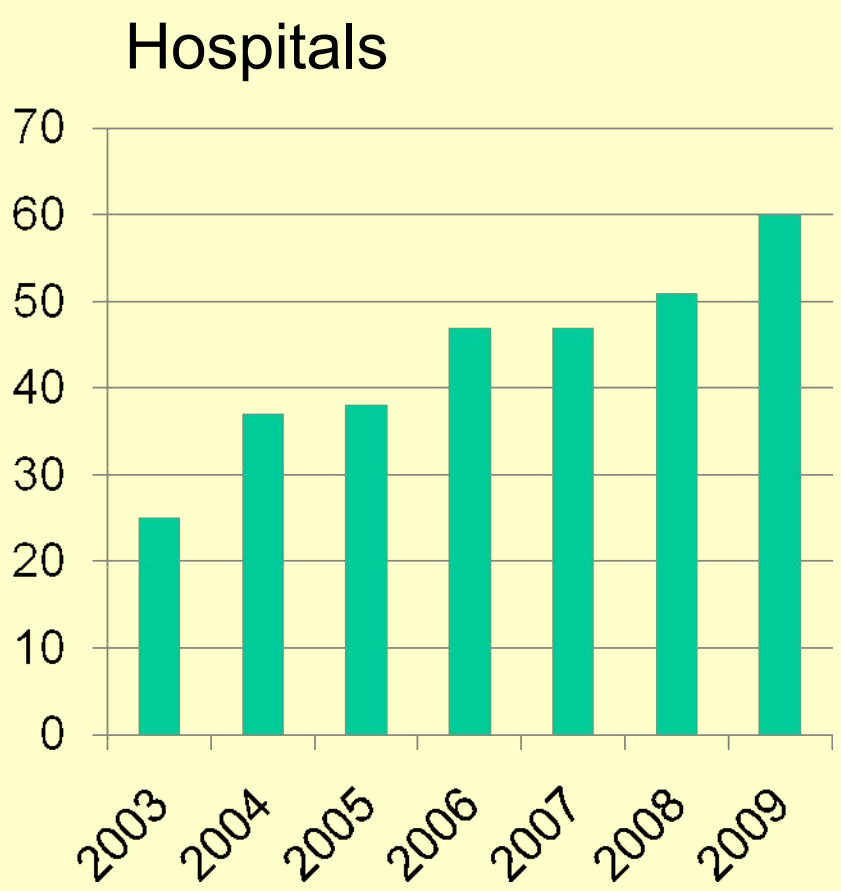


Number of reports of febrile reactions and allergic reactions per year, 2003 – 2009

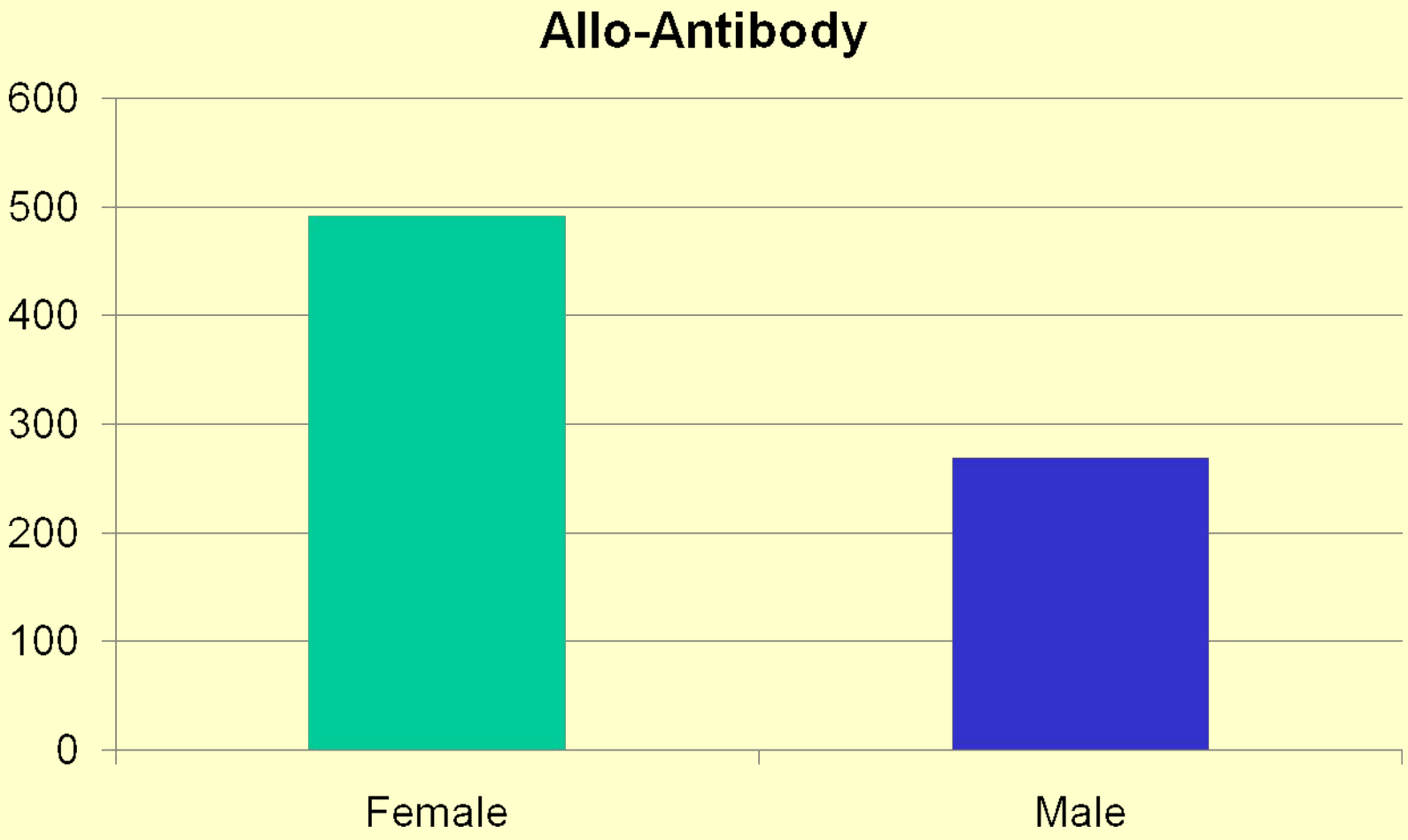


New Allo-Antibody Reports

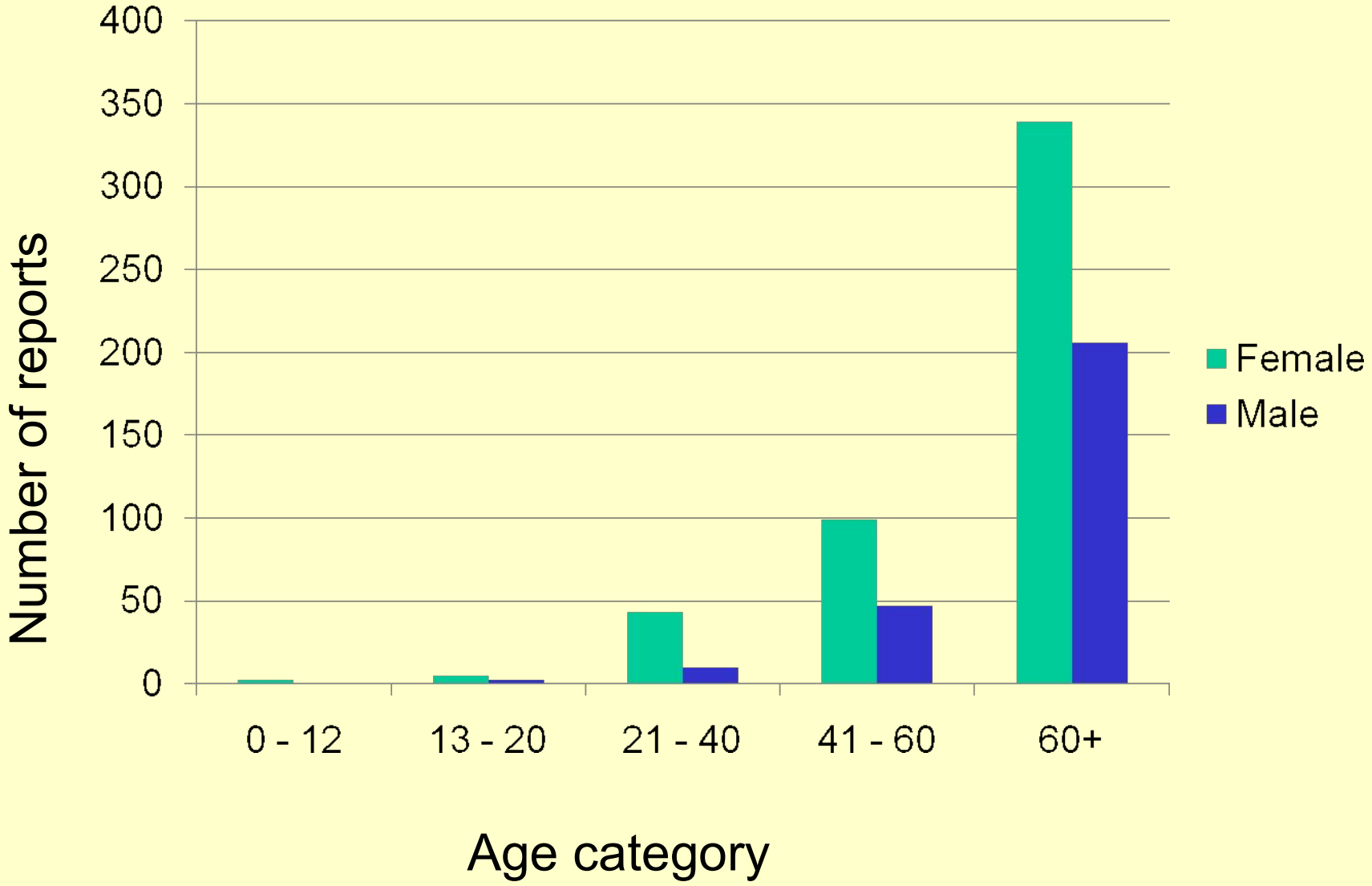




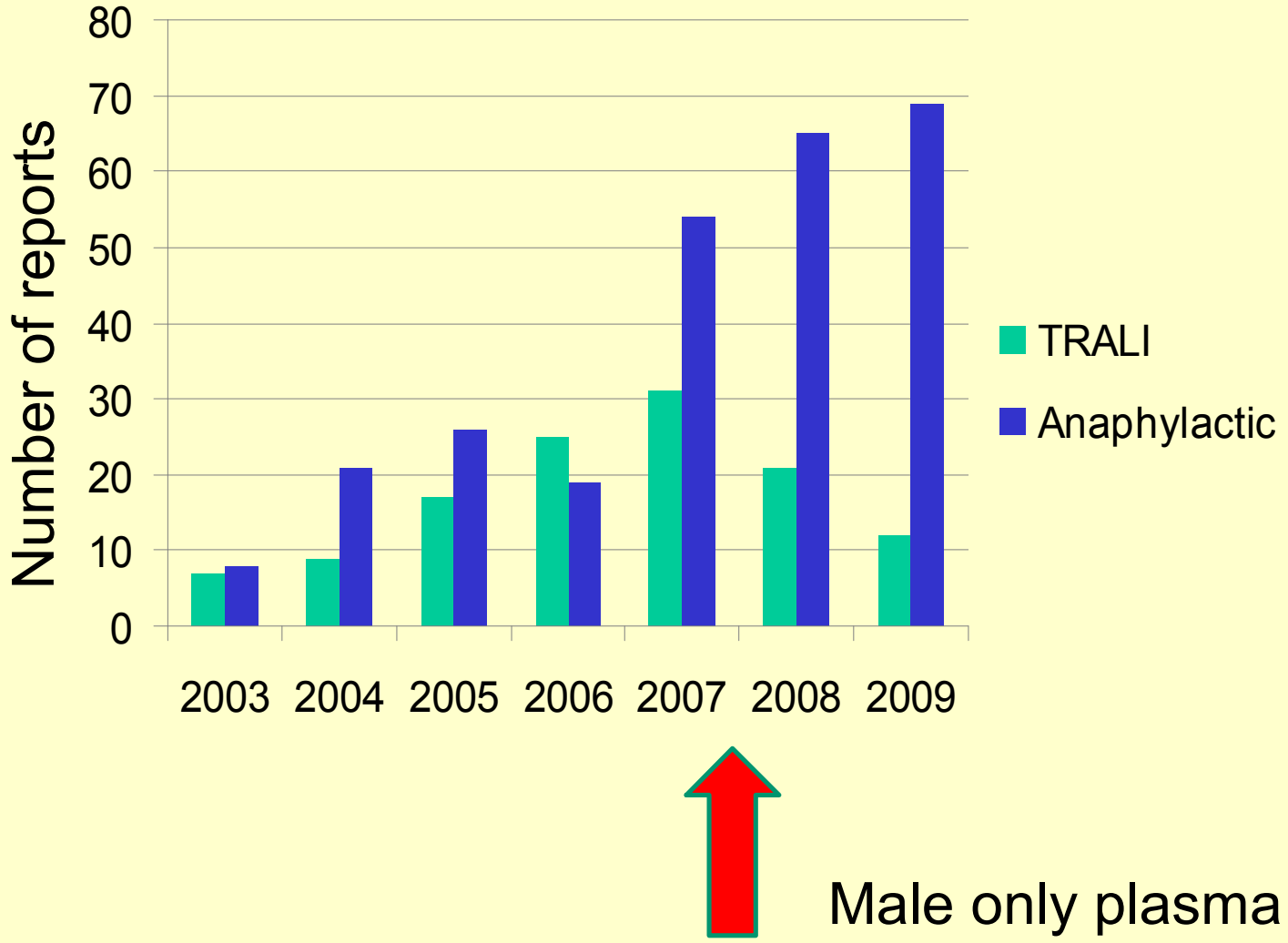
Sex distribution of allo-antibody formation



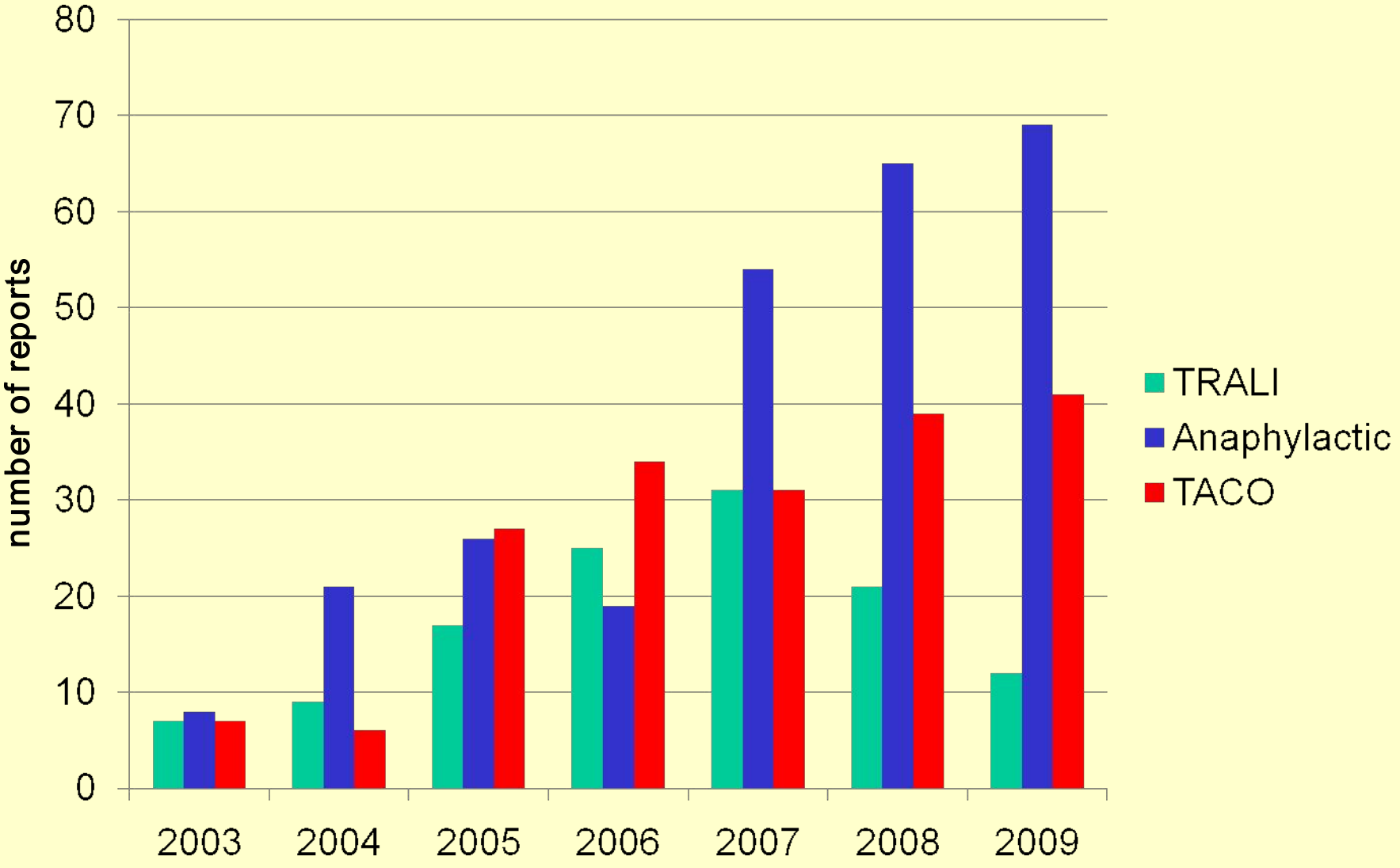
Age distribution of allo-antibody formation



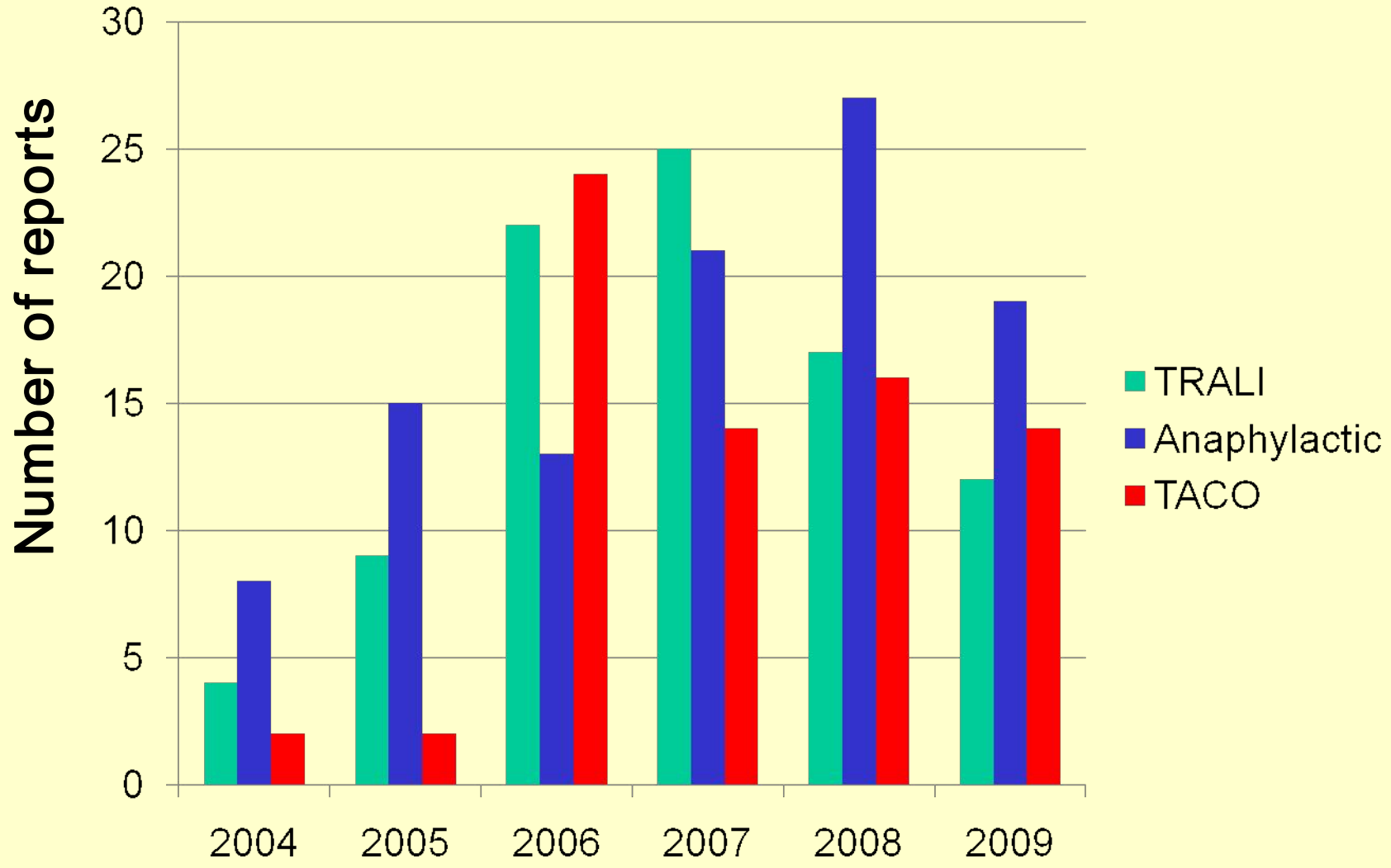
Total number of TRALI and Anaphylactic Reaction Reports in 2003 - 2009



Total number of TRALI, Anaphylactic and TACO reports



Grade ≥ 2 TRALI, Anaphylactic and TACO reports



TOP 3 Reports on Transfusion Reactions (total and ≥ grade 2)

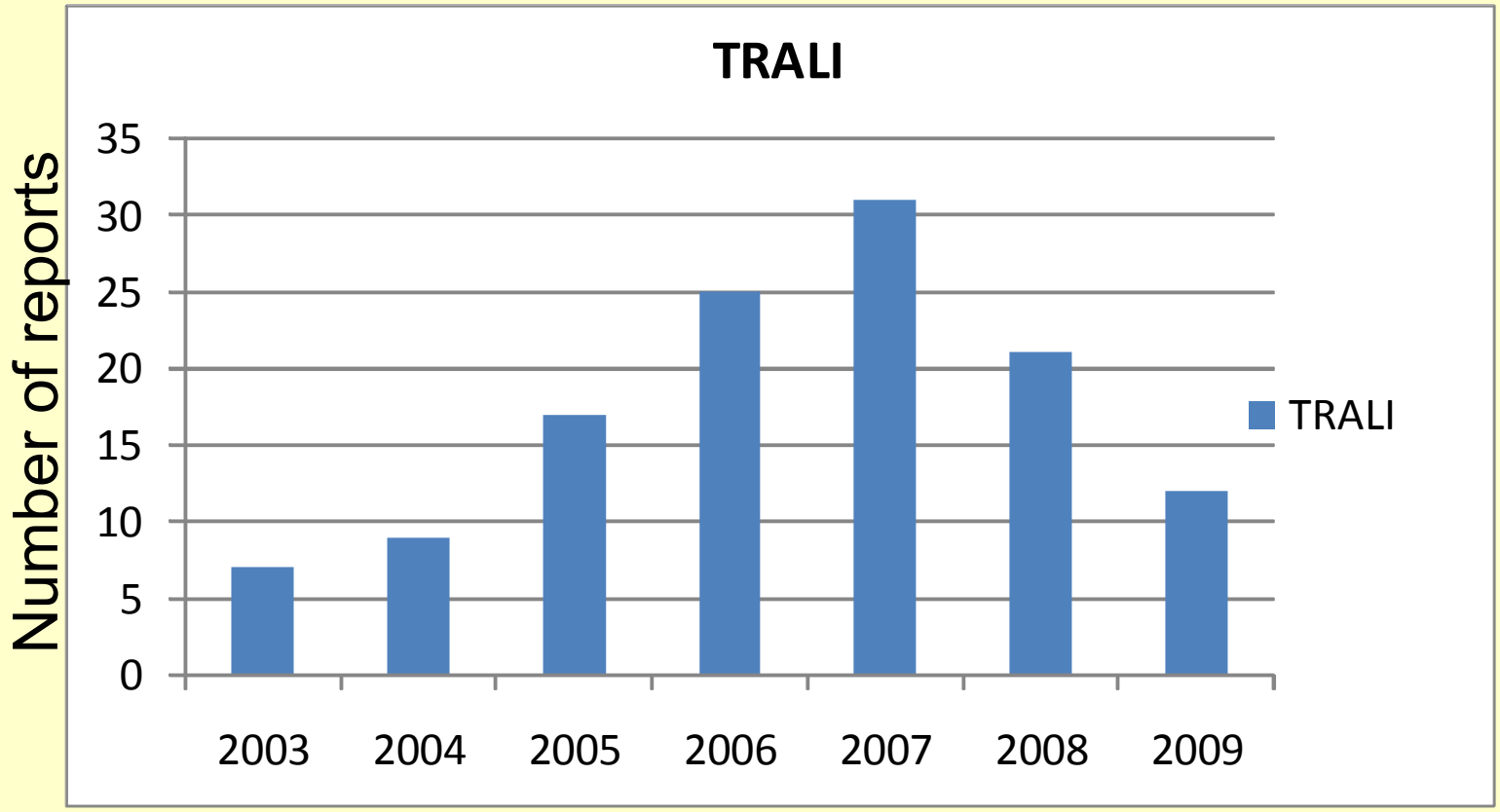
1. Anaphylactic reaction
2. TACO
3. TRALI

Conclusions

1. The total number of reports is higher than in previous years, particularly febrile reactions and reports of newly detected irregular antibodies.

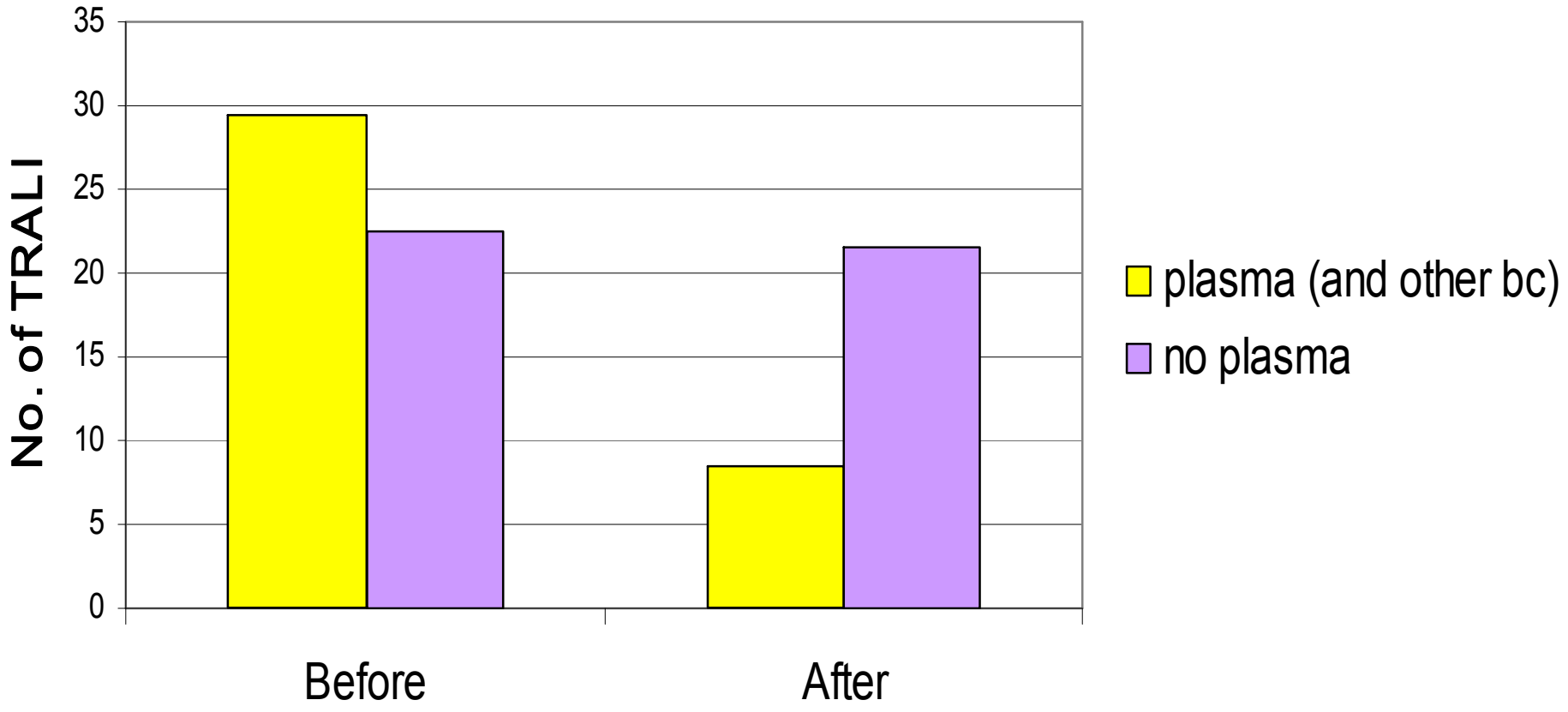
2. As a result of a decrease in the number of reported TRALIs and serious anaphylactic reactions, there has been a decrease in the total number of serious (≥ grade 2) reports.

Total number of TRALI Reports in 2003 - 2009



Male only plasma

Effect of the measure?



PAR: 0.33 (95% CI 0.09 to 0.51)

Excl. “possible TRALI”: 0.37 (0.06 – 0.58)

Wiersum-Osselton et al, Transfusion, in press

Positive outcomes for hemovigilance

- TRALI now recognized as a major cause of transfusion morbidity and mortality
- Implementation of the ‘male-only plasma’ measure
- Hemovigilance is an effective tool to monitor the impact of blood safety initiatives

Focus on Dyspnoea

TRIP reports 2005-2009

TRALI 107 (46x ECs; 12x TCs)*
9 reports no clinical information

=> TRALI + clinical info 98
- Rise in temp 20
  - + chills/rigors 3 (5 reports only chills/rigors)

TRALI with rise in temp 20 (11x ECs; 3x TCs)
- Δ temp not specified 8 (2 reports also chills/rigors)
- Δ temp < 1 1
- Δ temp >1<2 8
- Δ temp >2 3 (1 report also chills/rigors)

TRALI with chills/rigors 5 (1x ECs; 2x TCs)

* 44x combination of products, 5x only plasma

TRIP reports 2005-2009

TACO	173 (128x ECs; 16x TCs)*
26 reports no clinical information	
=> TACO + clinical info	147
➢ Rise in temp	38
➢ + chills/rigors	6 (9 reports only chills/rigors)
TACO with rise in temp	38 (29x ECs; 3x TCs)
Δ temp rise not specified	3 (1 report also chills/rigors)
Δ temp < 1	4 (1 report also chills/rigors)
Δ temp >1<2	21 (2 reports also chills/rigors)
Δ temp >2	10 (2 reports also chills/rigors)
TACO with chills/rigors	9 (1x ECs; 6x TCs)

* 15x combination of products, 11x only plasma, 1x drainblood, 2x not known

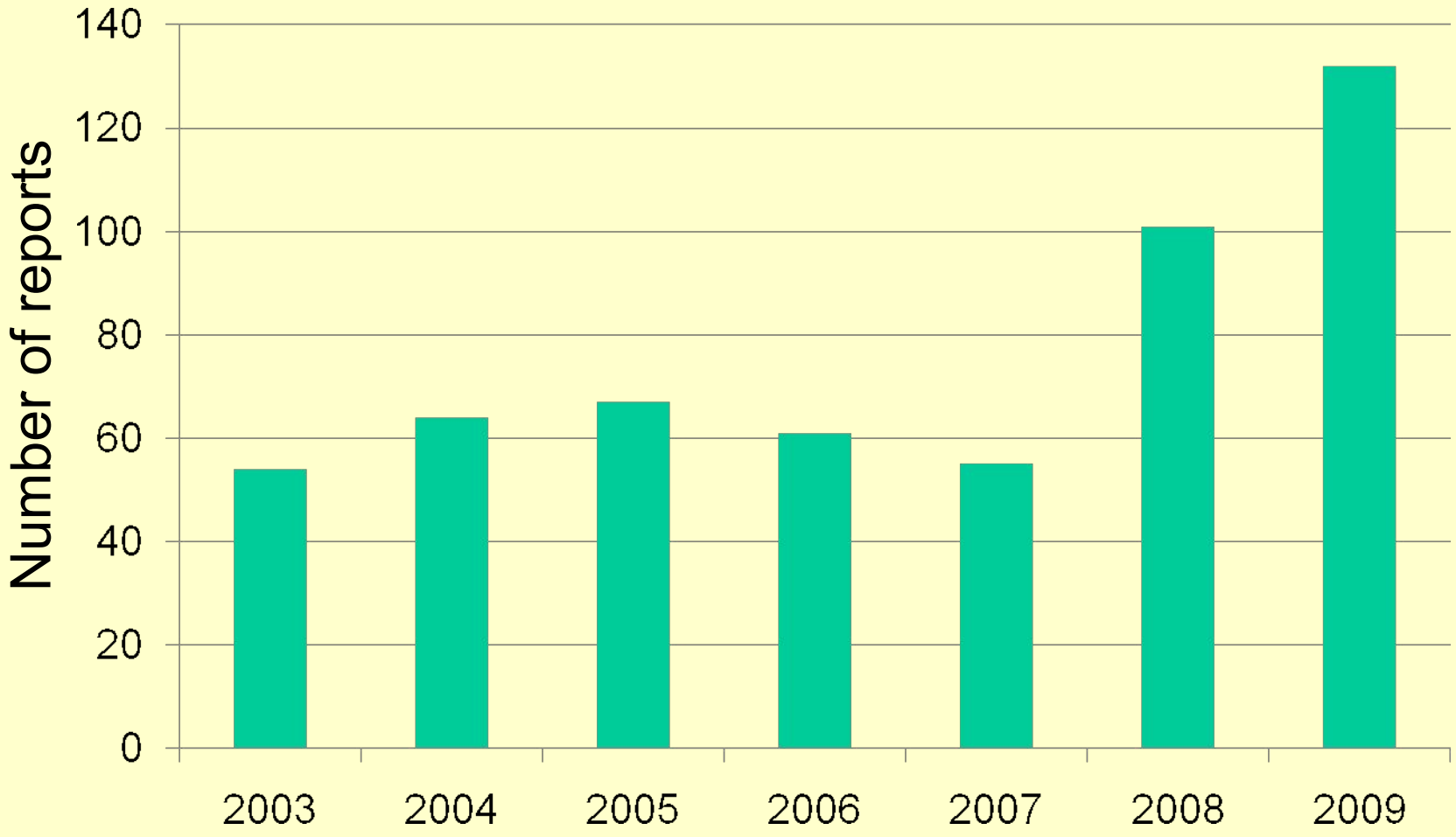
TRIP reports 2005-2009

AHTR + clinical info	66
➢ hypertension	4
➢ hypotension	9
IBCT => AHTR + clinical info	16
➢ hypertension	2
➢ hypotension	1
TRALI + clinical info	98
➢ hypertension	3
➢ hypotension	21
TACO + clinical info	147
➢ hypertension	32
➢ hypotension	12

Differential Diagnosis of Dyspnoea

- TACO, TRALI, Anaphylactic Reaction or Other Reaction
- Difficult to make the diagnosis!
- No additional diagnostic test available (proBNP?)
- A clinical diagnosis

Number of reports on ‘Other Reaction’



Diagnosis at the bedside

Goals for hemovigilance

- Full standardization of definitions
- Standardization is the only way in which meaningful benchmarking and pooling of data can occur
- Data capture of signs and symptoms at the bedside

Changing Paradigms

- From: focus on products: safety, efficacy, availability.

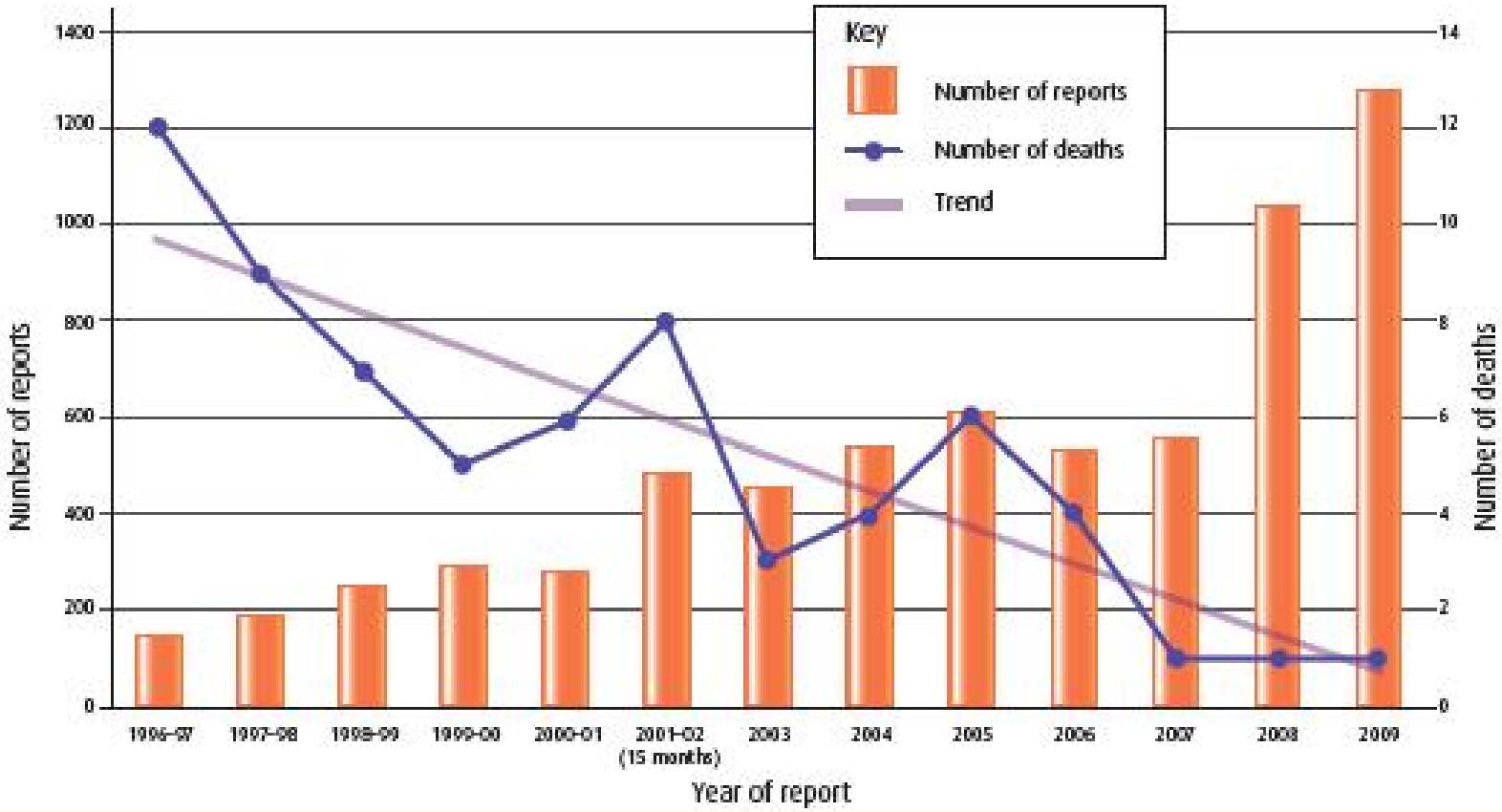
- To: focus on patients: hemovigilance as part of overall patient care

Hemovigilance and safety of blood transfusion

Limitations of the TRIP scheme ?

SHOT: total deaths due to transfusion

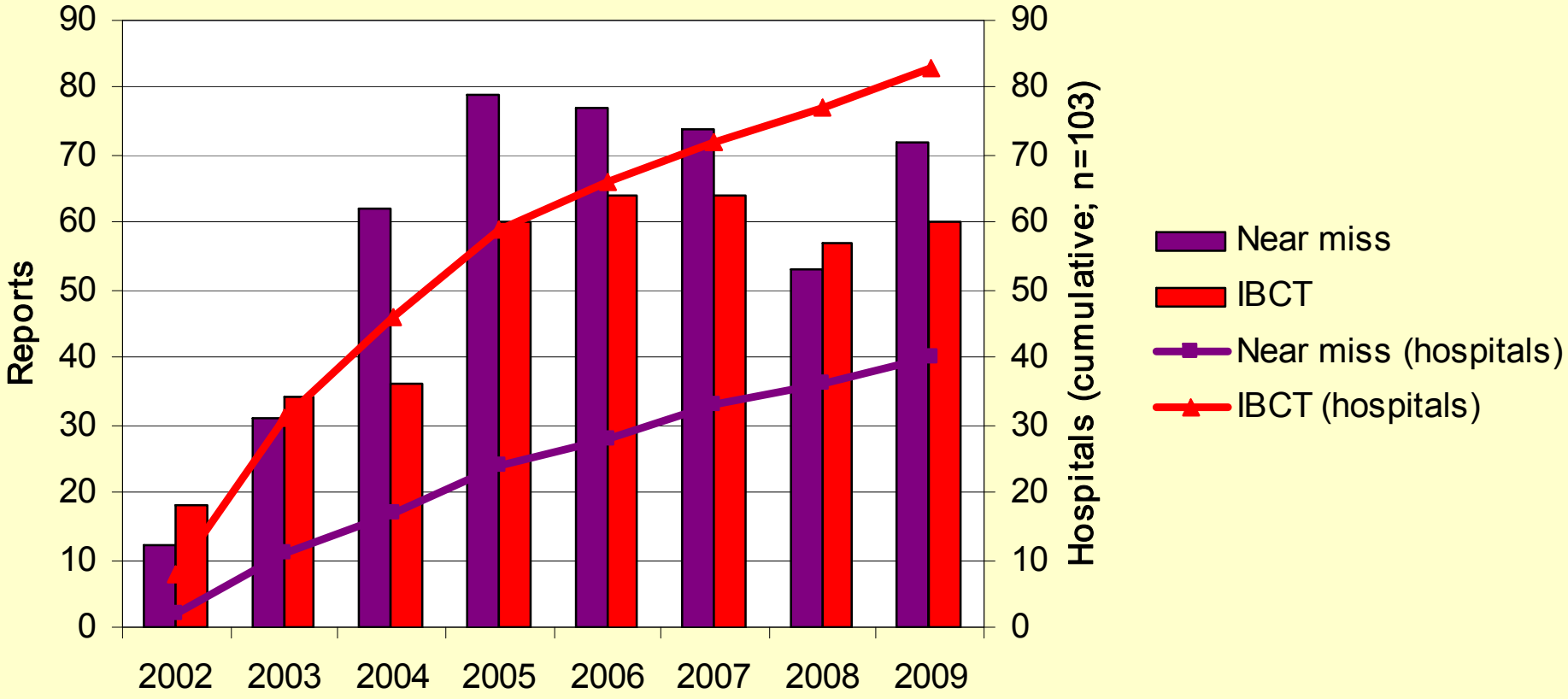
Figure 1
Total reports and total deaths definitely due to transfusion between 1996 and 2009



SHOT report 2009

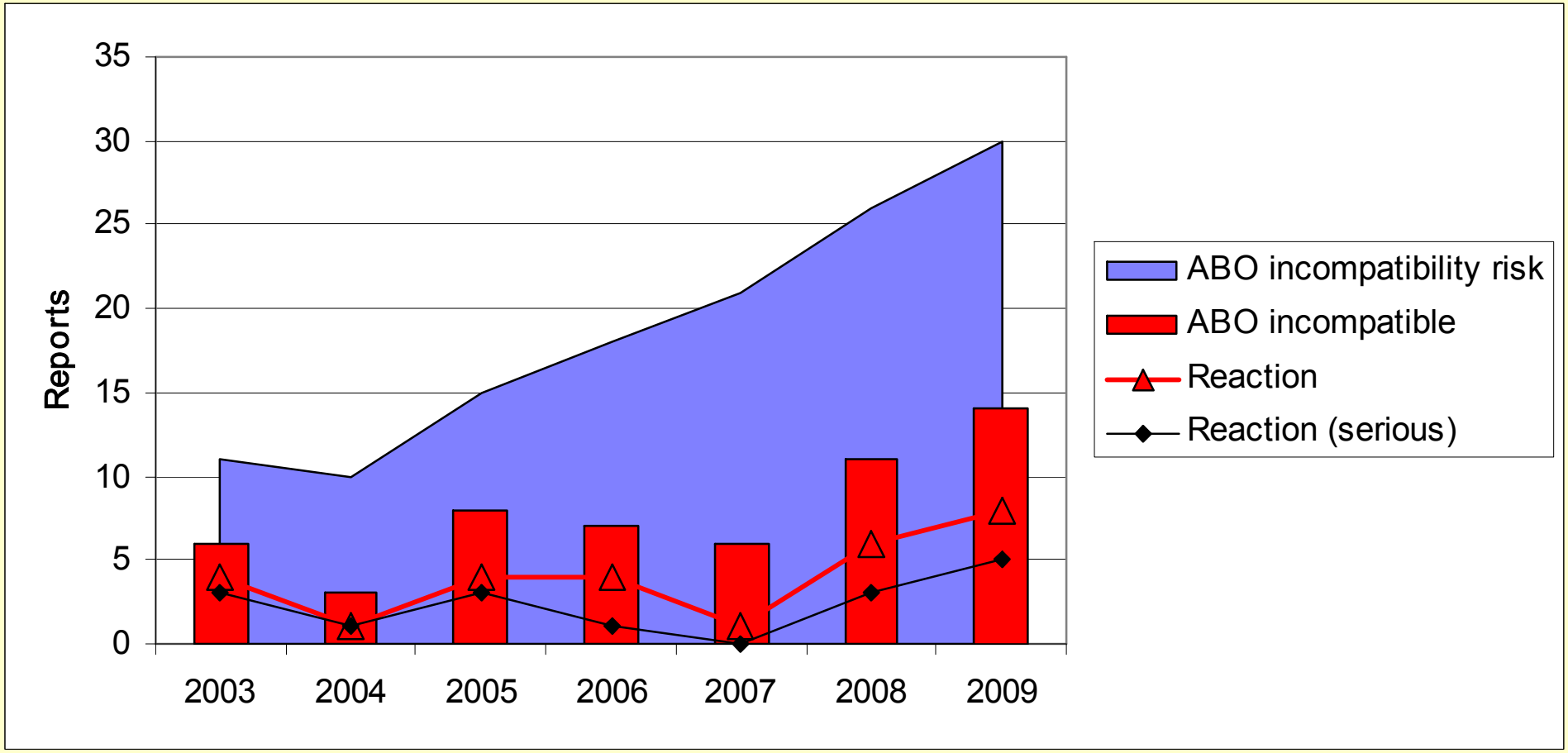
"These trends are the hallmark of an effective vigilance system, in that the participation in the scheme, and thus total reports, increases as users become engaged with the process while the number of serious incidents declines.."

Incident reports to TRIP



Reporting to TRIP is the professional standard. Near miss reporting encouraged.

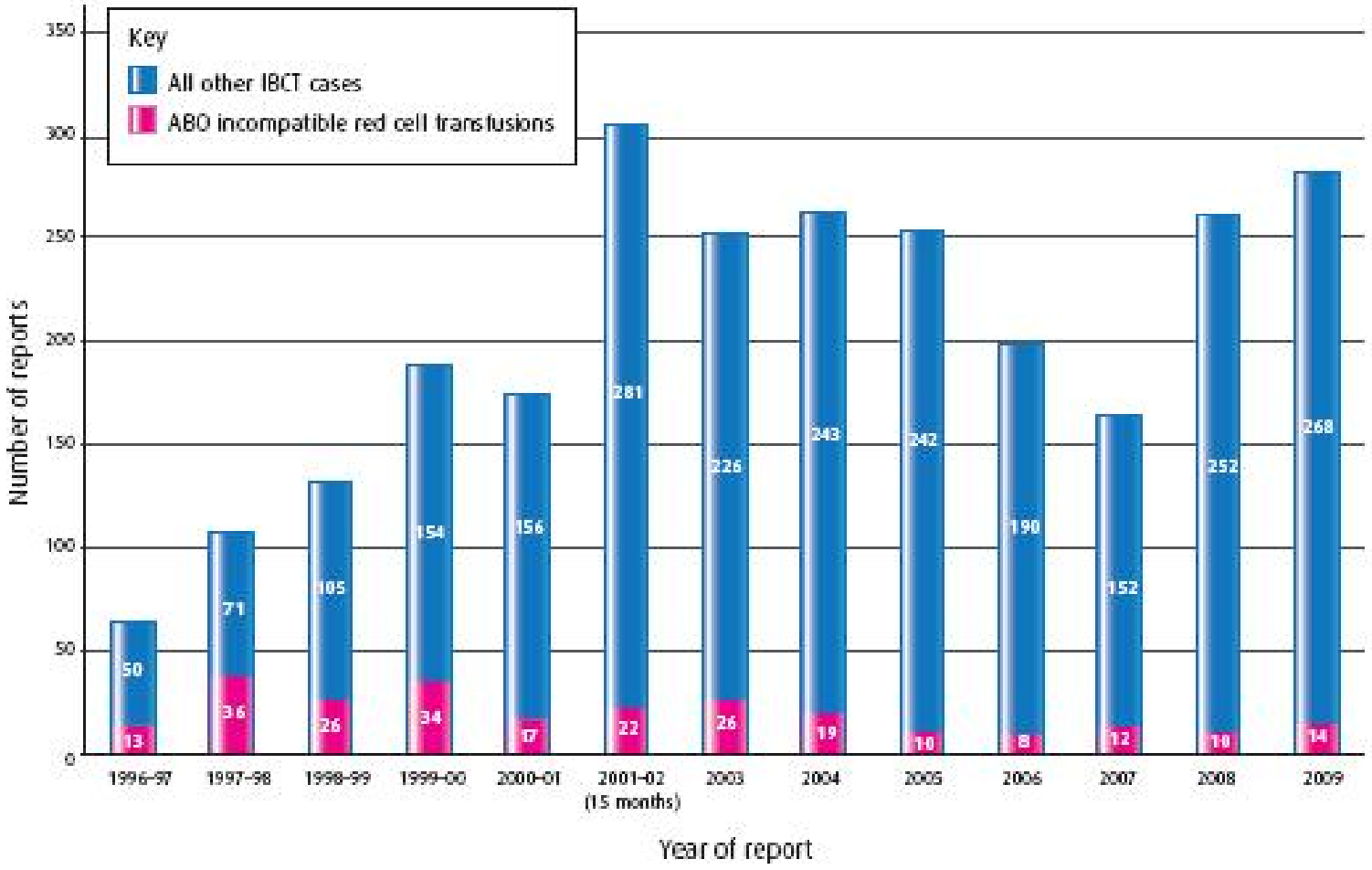
ABO incompatible transfusion



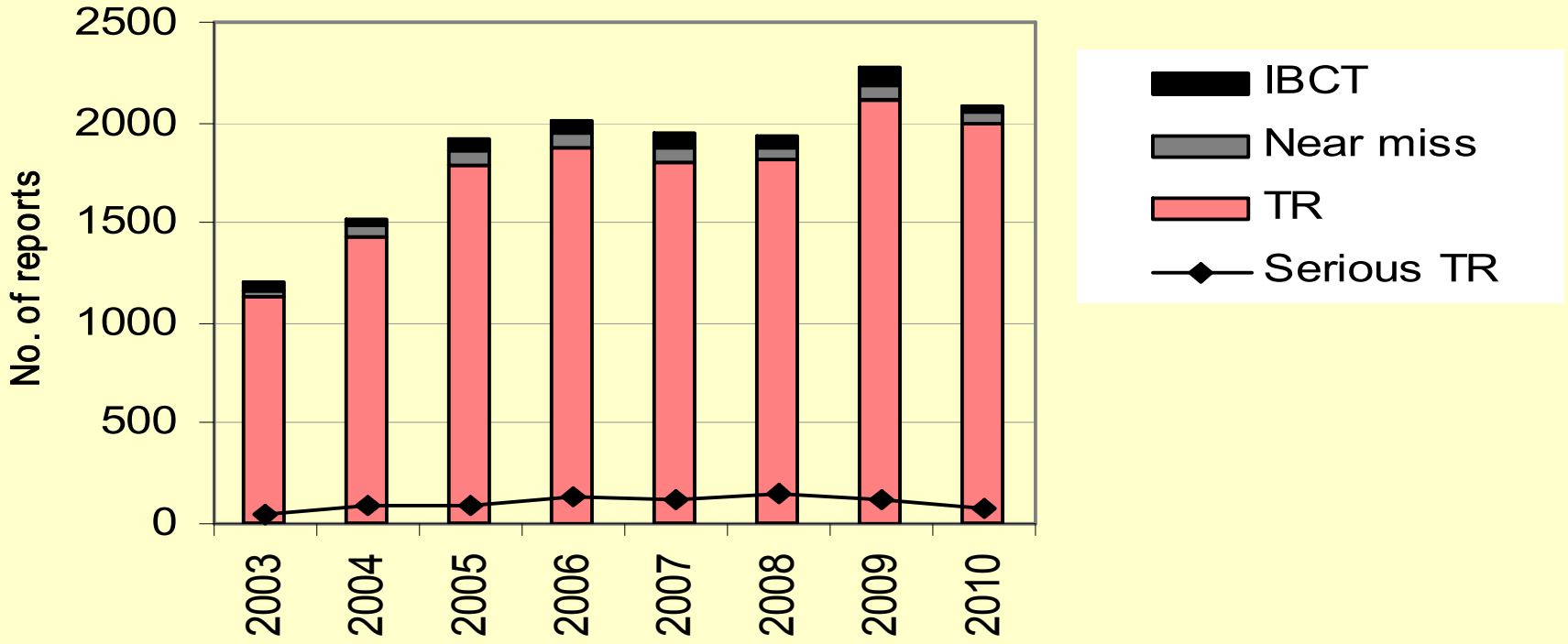
Note: in the first years of reporting to TRIP, information was less complete

SHOT: ABO incompatible transfusion

Figure 7
IBCT cases 1996–2009 showing ABO-incompatible transfusion
NB HSE and I&U cases are no longer included in the IBCT total (see 2008 Report) and are removed from the IBCT totals in this chart from 2003 onwards.



TRIP an effective hemovigilance system?



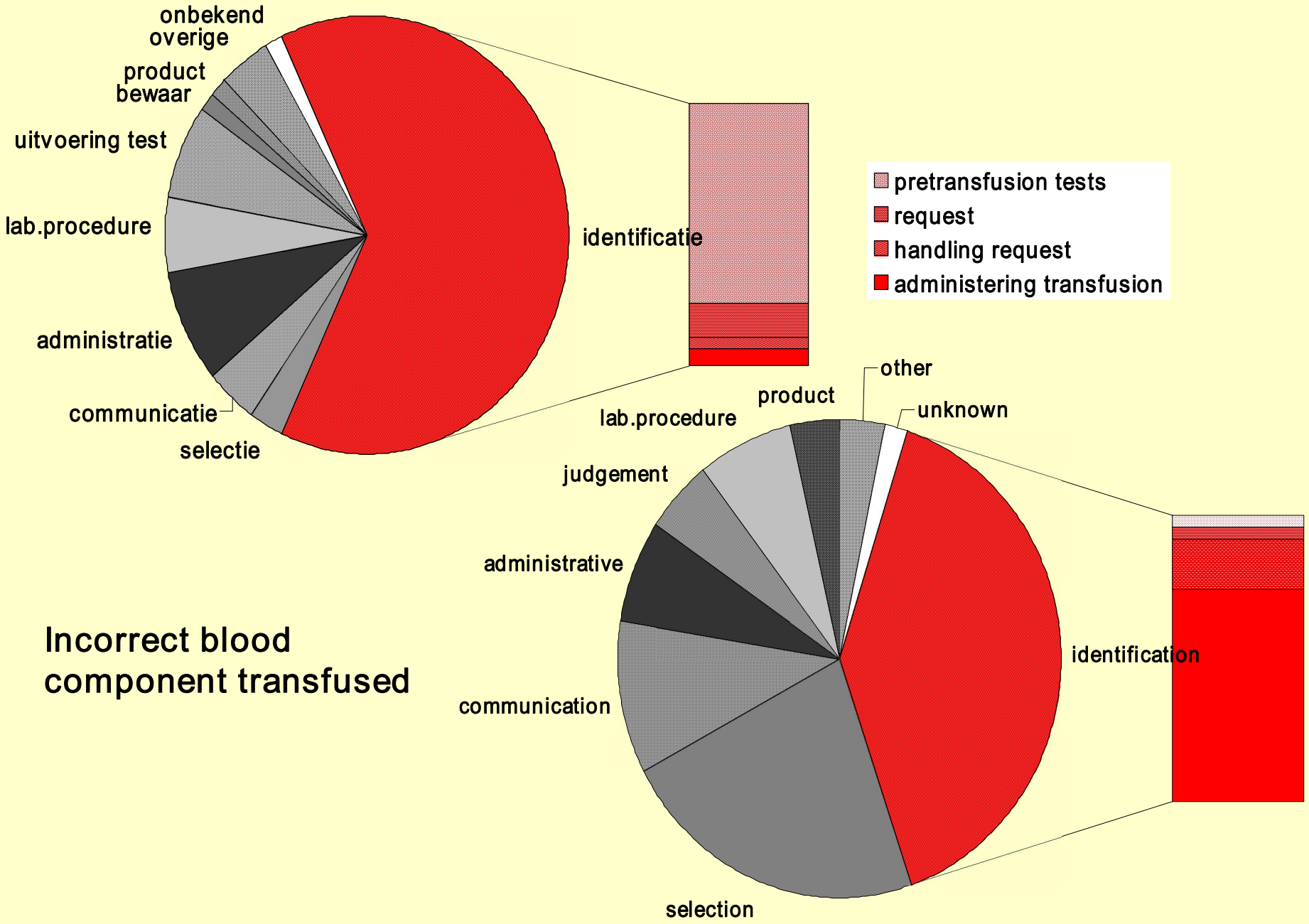
(figures excluding 192 reports still in assessment phase; 21 serious)

Conclusion

- TRIP does not see a sustained decrease in the number of serious TR
- Spontaneous reports are not a good way of measuring incidence

Near miss

Incident reports 2009: type of first error



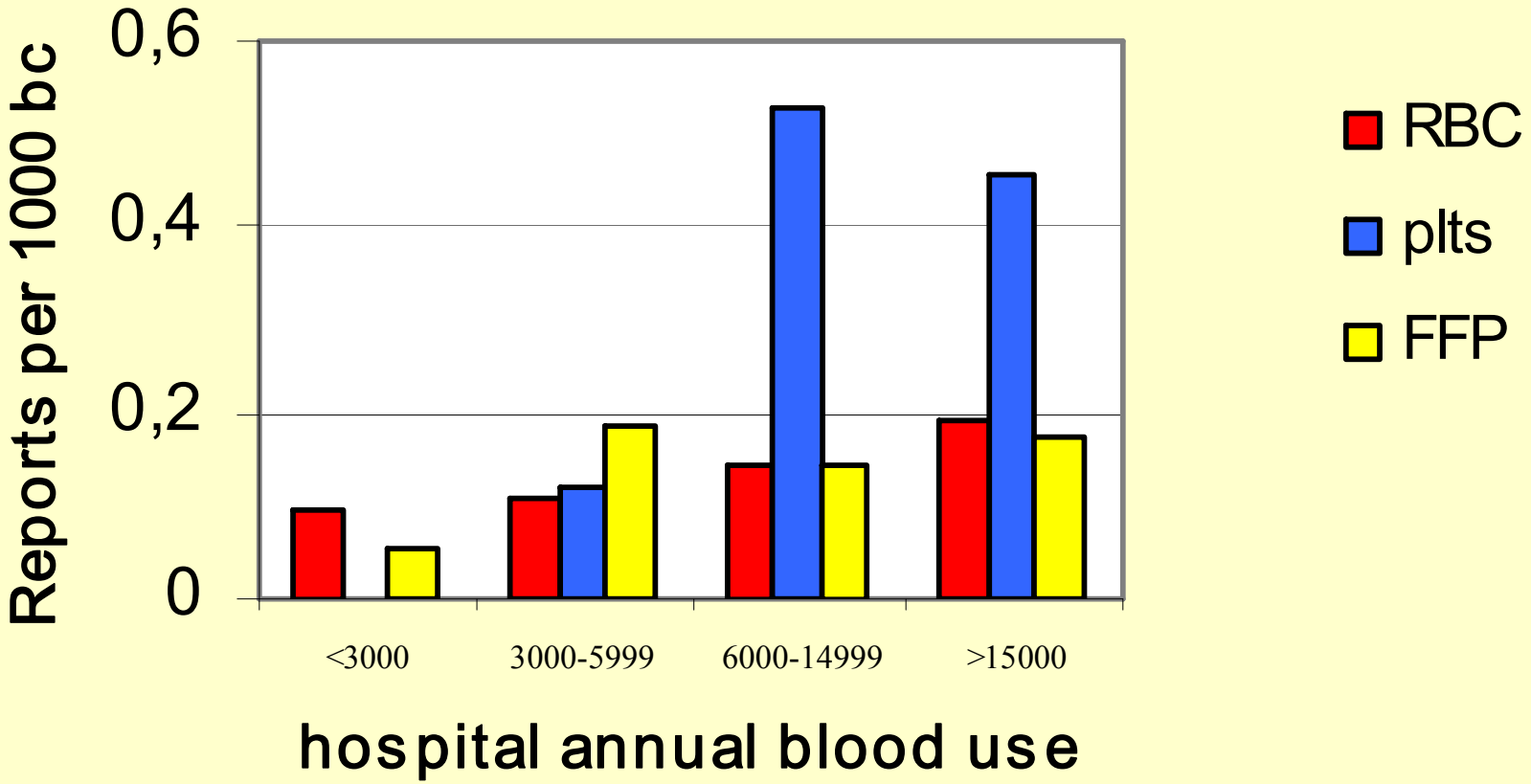
Incorrect blood component transfused

For identification errors

No effective measures have been taken yet!

Serious transfusion reactions (2006-8)

(definite, probable, possible)



TRANSFUSIE REACTIES IN PATIËNTEN

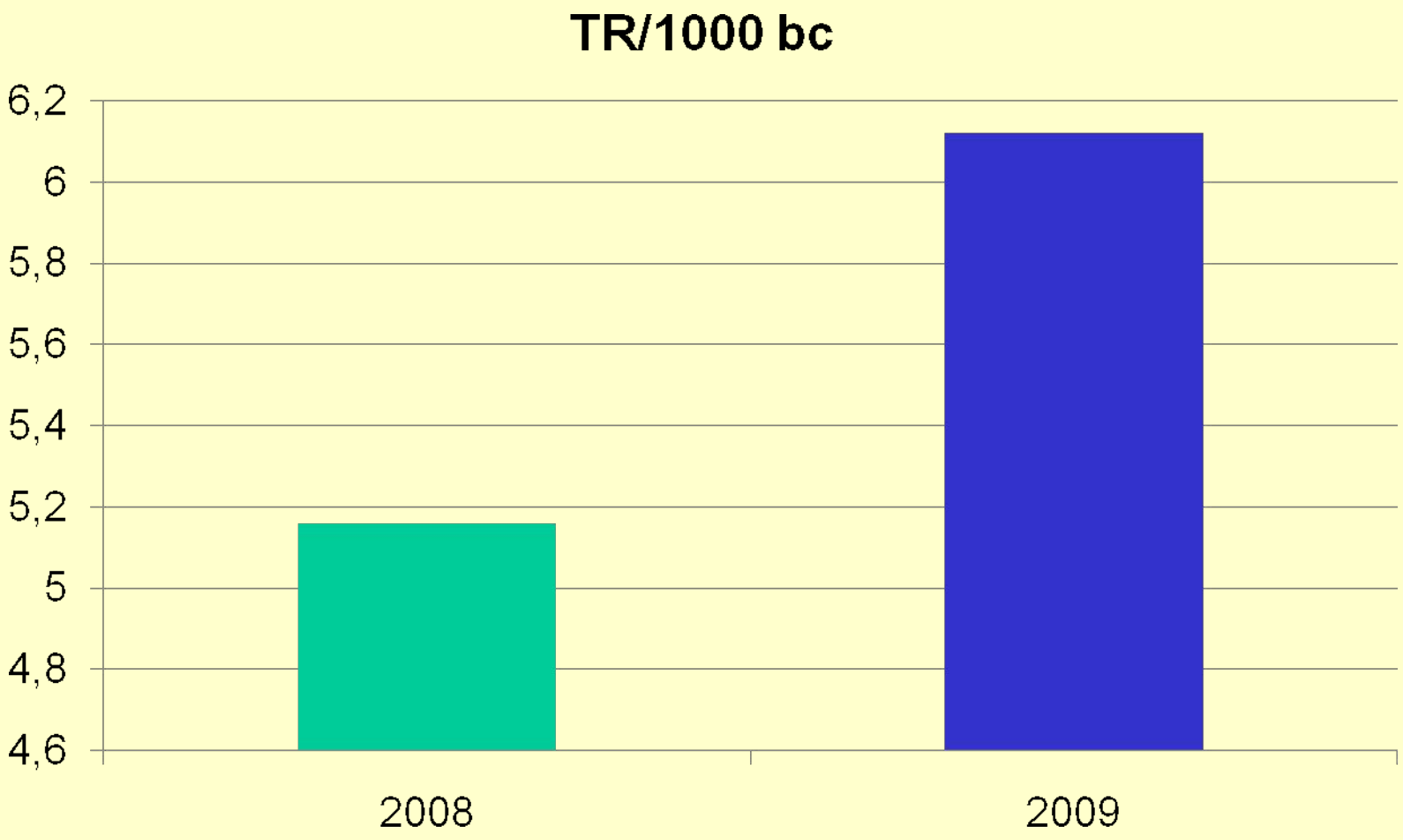
T R I P

Table 3 Number of reports per type of blood component in 2008 and 2009

Type of blood component (bc)	2008 Number of bc supplied	2008 Reports; number per 1000 bc		2008 Serious reports#; number per 1000 bc		2009 Number of bc supplied	2009 Reports; number per 1000 bc		2009 Serious reports#; number per 1000 bc	
Red blood cell concentrate	559,372	1518	2.71	79	0.14	559,976	1812	3.24	63	0.11
Platelet concentrate	50,784	262	5.16	26	0.51	49,354	302	6.12	18	0.36
Fresh frozen plasma	96,622	81	0.84	11	0.11	90,390	99	1.10	8	0.09
Autologous (RBCs, pre-deposit)	110 dona-tions	1		0		No info	1		0	
Cell-saver and drain blood		24		1			32		3	
Other products		4		0			0		0	
Combinations		95		14			70		6	
Not stated		79		1			68		0	
Total	706,868	2053	2.90	132	0.19	699,720	2384	3.41	98	0.14

Imputability certain, probable, possible

Number of reports for platelet concentrates



HOVON 82

Clinical effectiveness of pooled, random donor platelet concentrates, stored in either plasma or additive solution with and without pathogen reduction in hemato-oncological patients

J.L.H. Kerkhoffs[1, 4], V.M.J. Novotny[2], P.A.W. Te Boekhorst[3], M. Schipperus[4], J.J. Zwaginga[5], E.C.M. van Pampus[2], W. van Putten[6], M. Luten[6], P.C. Huijgens[7], A. Brand[1], D.J. van Rhenen[1] on behalf of the Dutch – Belgian HOVON cooperative group.

[1] Sanquin Southwest Region, Rotterdam; [2] Radboud University Medical Centre, Nijmegen; [3] Erasmus Medical Center ,Rotterdam; [4] Haga Teaching Hospital, The Hague; [5] Leiden University Medical Center, Leiden; [6] HOVON Data Center, Rotterdam; [7] VU Medical Center, Amsterdam, The Netherlands.

Secondary endpoints HOVON 82

	Plasma N = 99	PAS-III N = 94	PR-PAS-III N = 85
PLT Transfusions / patient	4 ±2	4 ±3	5 ±3[2]
RBC Transfusions / patient	4 ±3	5 ±3	4 ±3
Transfusion interval (hours)	81 ±47	77 ±44	61 ±47[1]
Bleeding			
Before the first PC (%)	13	13	15
after the first PC (%)	19	16	33[3]
Infection (%)	40	42	49
Adverse transfusion reaction (%)	11	6	6
SAE (%)	7	3	6

[1]p = 0.001; [2]p = 0.01; [3]p = 0.04 as compared to plasma

Conclusion

- An active reporting system (like in a RCT) results in a ten times higher number of transfusion reactions
- Monitoring and audits should be introduced in the hemovigilance schemes.

General concluding remarks

- The total number of reports is higher than in previous years, mainly due to an increase in non-serious reactions (NHFR and Allo-antibodies)
- There has been a decrease in TRALI cases since the introduction of ‘male-only plasma’
- Anaphylactic reaction is now the largest category of serious transfusion reaction

Concluding remarks 2

- There has been no decrease in the number of reports of incidents in which the patient was exposed to a potentially incompatible transfusion. Identification of patients, patient material and blood components remain error-prone processes.

- An intervention is needed !

Concluding remarks 3

- Reports listing the most important symptom as dyspnoea or hypotension form two important clusters in the category ‘other reaction’. Sometimes there are insufficient investigations and clinical information to make an adequate diagnosis of the transfusion reaction. As a result, increasing numbers of reactions are labelled ‘other reaction’.

Hemovigilance

- Identifies issues
- Informs decision making
- Supports priority setting and resource allocation
- Is an effective method to monitor the impact of interventions to improve transfusion safety
- Needs better standardization of definitions and a more effective (bed side) data capture system

Members of TRIP Governing Board	On behalf of
M.R. van Bohemen-Onnes	Verpleegkundigen & Verzorgenden Nederland (nurses and nursing care professionals)
A. Brand	Dutch Society of Specialists in Internal Medicine
J.L.P. van Duijnhoven	Dutch Society for Clinical Chemistry and Laboratory Medicine
F.J.L.M. Haas	Society for Hematological Laboratory Investigation (till Jan. 2009); advisor
P.C. Huijgens	Dutch Hematological Society (till Jan. 2010)
I.L. van Kamp	Dutch Society for Obstetrics and Gynaecology
A.W.M.M. Koopman-van Gemert	Dutch Society for Anaesthesiology and Intensive Care Medicine
J.H. Marcelis	Dutch Society for Medical Microbiology
V.M.J. Novotny	Dutch Society for Hematology (from Jan. 2010)
M.A.M. Overbeeke	Dutch Society for Blood Transfusion
C.L. van der Poel	Sanquin Medical Adviser
J.W.P.H. Soons	Society for Hematological Laboratory Investigation (from Jan. 2009)
E.L. Swart	Dutch Society of Hospital Pharmacists
J.P.P.M. de Vries	Dutch Surgical Society
R.R.P. de Vries	Transfusion Medicine in University Hospitals
R.Y.J. Tamminga	Dutch Pediatric Society

Advisory Board

R.M.Y. Barge	Dutch Federation of University Hospitals (till Jan. 2010)
J.M.M. Hansen (reading member)	Chief Inspector IGZ (Healthcare Inspectorate)
R. Treffers	Dutch Association of Hospitals
H.J.C. de Wit	Governing Board, Sanquin

Patroness

E.J.G.M. Six – Baroness van Voorst tot Voorst

Expert Committee

A. Brand, F.J.L.M. Haas, J.H. Marcelis, M.A.M. Overbeeke, M.R. Schipperus, R.R.P. de Vries
Additional advice was provided by C.P. Henny, A.W.M.M. Koopman-van Gemert and R.Y.J. Tamminga.

TRIP Office

M.R. Schipperus	Director
J.C. Wiersum-Osselton	National Coordinator
A.J.W. de Jong-van Tilborgh	Senior Hemovigilance physician
P.Y. Zijlker-Jansen	Hemovigilance and tissue vigilance physician
M.J. Happel-van 't Veer	Tissue vigilance project coordinator


TRIP works !