

Hemovigilance in Québec

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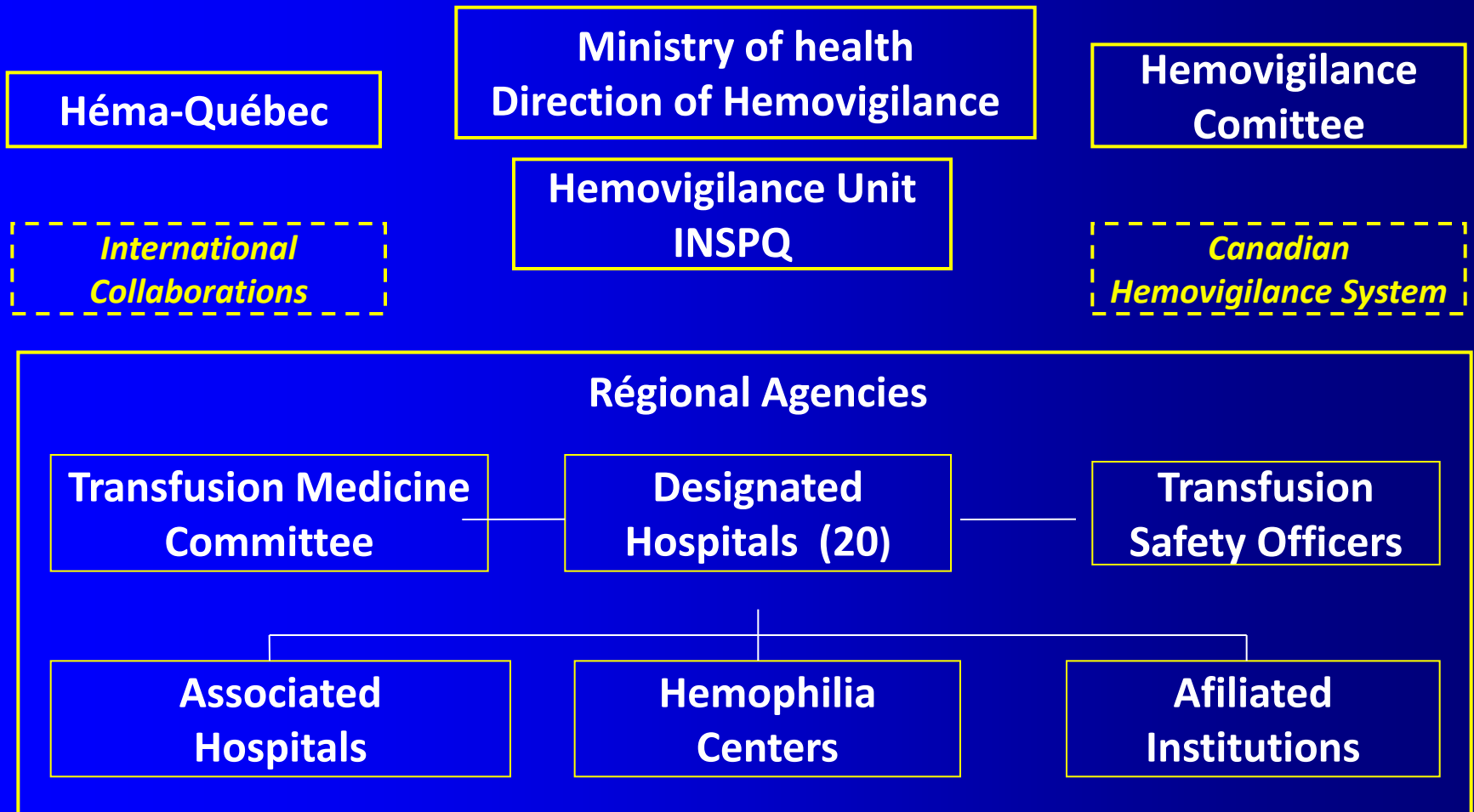
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Quebec Hemovigilance System



Methods

- Network of 20 designated hospitals oversee transfusion activities in Québec.
- Centralized reporting system of ATEs was implemented in 2000.
- Voluntary reporting system for transfusion errors and reactions (blood components and plasma derivatives products)

Methods

- Bedside or blood banks health professionals must recognize and initiate a reporting of ATEs.
- Transfusion safety officers in the designated hospitals are responsible for investigating and reporting ATEs.
- Standardized definitions for each data element including diagnosis of ATR are used.
- Diagnosis and association with transfusion are established by medical blood bank directors.
- Data without patient identification are transferred to the QHS (electronically since apr 2001)

Methods

- Data are validated at the provincial level for accuracy and completeness.
- Further validation of all serious reactions by physician at the Québec Public Health Institute and consultant hematologist, for concordance with standard definitions.
- Actual number of units transfused as per hospital monthly reports to Québec Health Ministry are used for incidence calculations.
- Analyses done using SPSS software, EPI-INFO software, OpenEpi Epidemiologic calculator

Definitions

➤ Incident

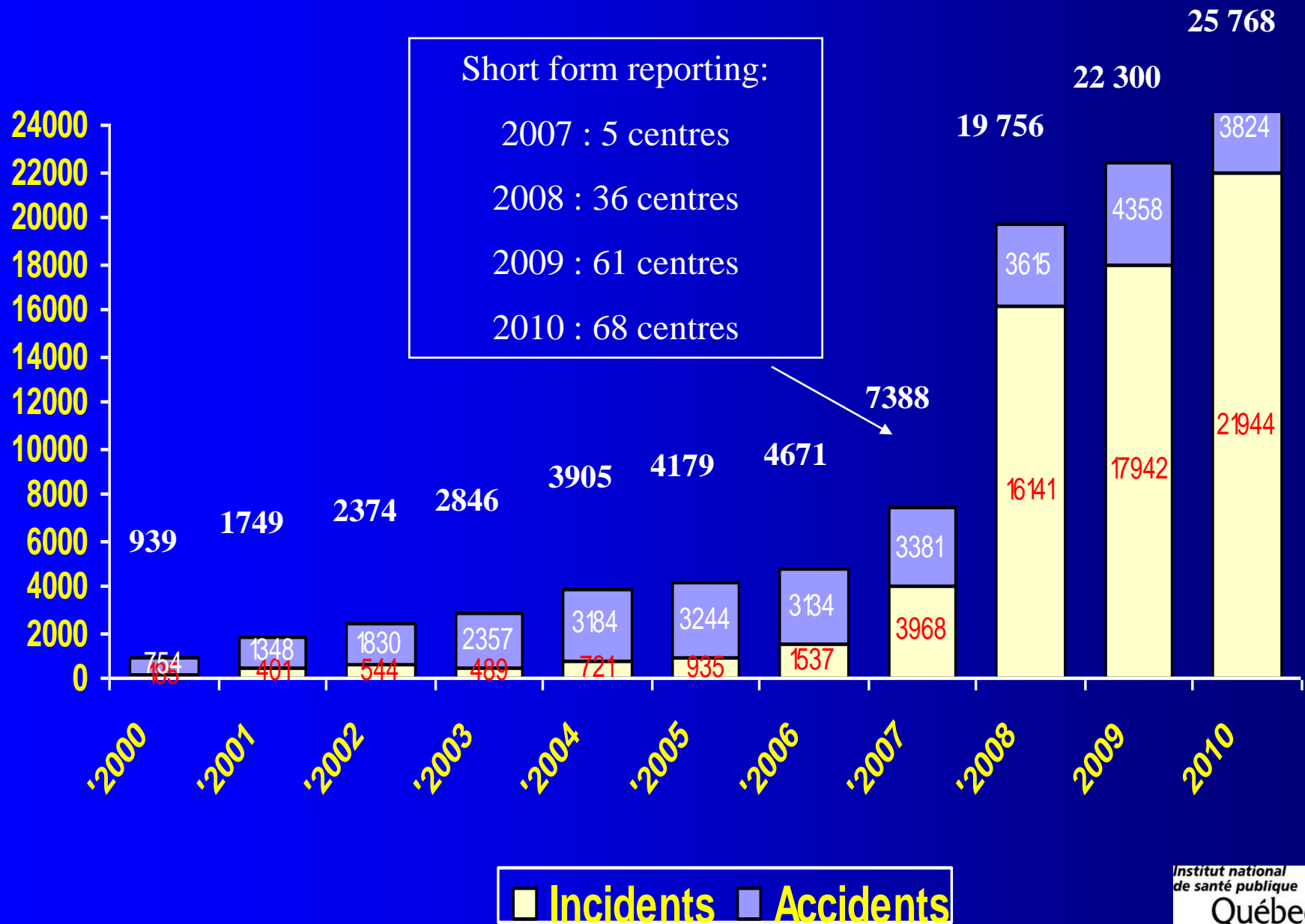
- Error or problem identified before transfusion

➤ Accident

- Error identified after start of transfusion
- Adverse transfusion reaction

Incidents and Accidents

Trends in reporting



Transfusion coverage

2010

84 centers reported 25 768 transfusion events

- **19 Designated Hospitals**
- **56 Associated Hospitals**
- **9 Affiliated Institutions**

Coverage of transfusion activity in Québec :

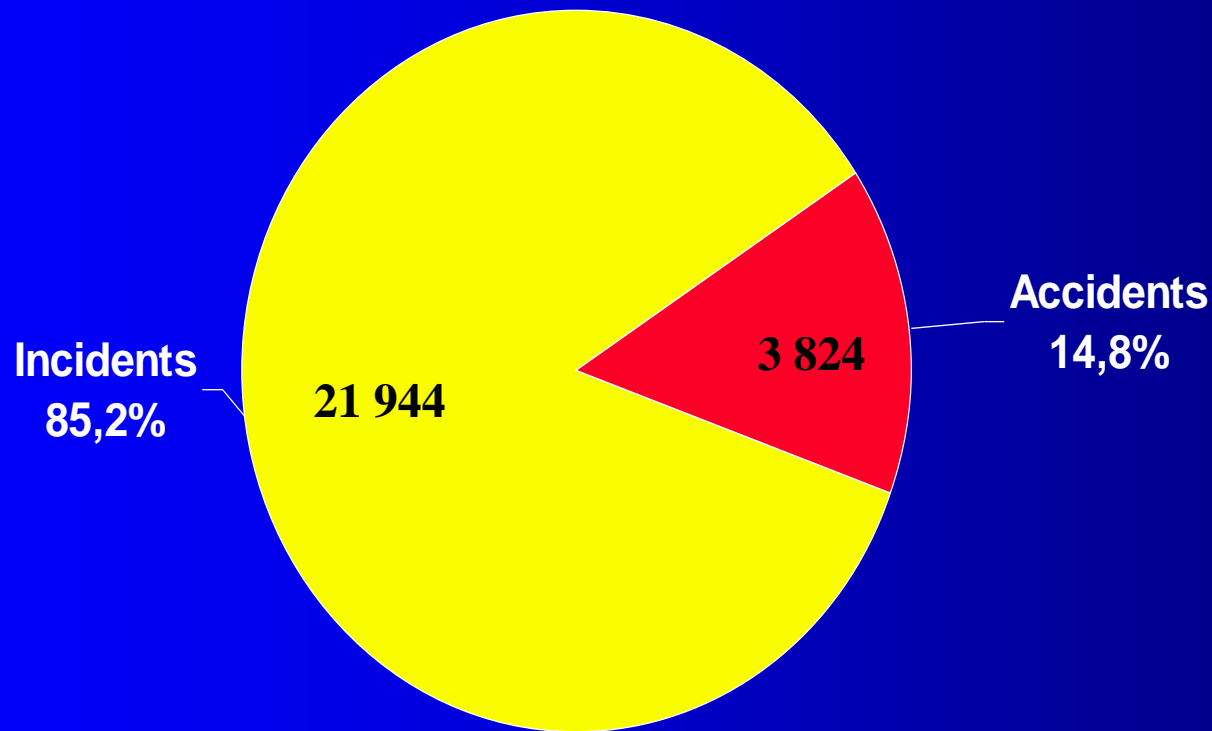
2008 : 99,9%

2009 : 93,6%

2010 : 82,1%



Incidents vs Accidents



N= 25 768

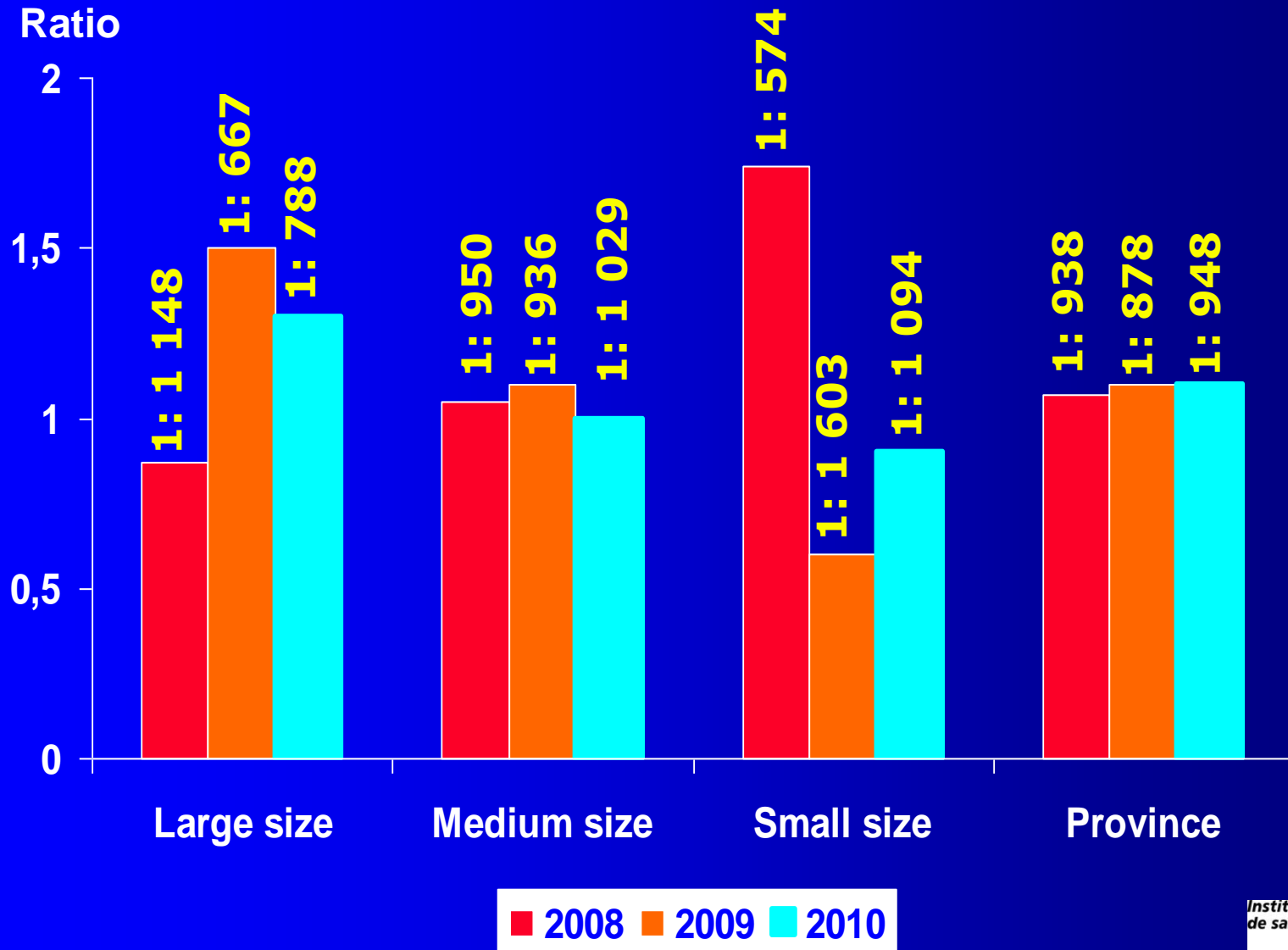
Incidents

	N	%
On wards	20 281	92.4
At the blood bank	837	3.8
Various locations	826	3.8
total	21 944	100.0

Incidents in 2009 - 2010

	2009			2010		
	N = 17 942			N = 21 944		
Incidents on wards	N = 16 881 (94,1%)			N = 20 281 (92,4%)		
	N*	%		N*	%	
Wrong blood in tube :	717	4,2	4,0	655	3,2	3,0
Wrong name on tube	454	2,7	2,5	368	1,8	1,7
Sample from wrong patient	124	0,7	0,7	123	0,6	0,6
Wrong name on tube + request	139	0,8	0,8	164	0,8	0,7
Label on tube did not respect standards	4941	28,8	27,0	4907	24,2	22,4
No label on tube	320	1,9	1,8	333	1,6	1,5
No label on request	370	2,2	2,1	410	2,0	1,9
Wrong name on request	151	0,9	0,8	148	0,7	0,7

Wrong blood in tube by hospital size 2008-2010



Incidents in 2009 - 2010

	2009			2010		
	N = 17 942			N = 21 944		
Other incidents on wards	N = 16 881 (94,1%)			N = 20 281 (92,4%)		
	N*	%		N*	%	
Hemolyzed sample	3033	17,7	16,9	3515	17.3	16.0
Request not respecting standards	1175	6,9	6,5	2184	10.8	10.0
Transfusion slip not appropriately completed	3069	17,9	17,1	4574	22.6	20.8
Unnecessary sample	2026	11.8	11.3	2329	11.5	10.6
Wrong product ordered	23	0,1	0,1	30	0.1	0.1
Product ordered for wrong patient	38	0,2	0,2	44	0.2	0.2

Incidents in 2009 - 2010

	2009			2010		
	N = 17 942			N = 21 944		
Incidents in blood bank	N = 765 (4,3%)		%	N = 837 (3,8%)		%
	N*	%		N*	%	
Technical error	155	20,3	0,9	207	24.7	0,9
Transcription error	40	5,2	0,2	34	4.1	0,2
Incorrect product labeling	10	1,3	0,1	5	0.6	0,02
Product issued for wrong patient	2	0,3	0,01	11	1.3	0,05
Wrong product issued	34	4,4	0,2	34	4.1	0,2
Produit distributed to wrong patient	17	2,2	0,09	5	0.6	0,02
Produit issued that did not meet patient requirements	13	1,7	0,07	17	2.0	0,1

Consequences of errors

2010

Consequences	N
Patient resampled	8 373
Products destroyed (793 errors)	944



Blood components destroyed

2010

Type of product	N of units	Cost (\$)
RBCs	435	151 875
Plasma	90	19 584
Cryo supernatant	63	13 679
Granulocyte	62	99 550
Whoole blood	55	19 092
Apheresis platelets	40	22 810
Pooled platelets	40	5 280
Total	785	331 873

Plasma derivatives destroyed

2010

Type of product	N of products	Cost (\$)
IVIg	102	139 719
Albumin	21	1 5193
Factor VIIa recombinant	12	13 566
IgIM	19	589
Anti-D	4	324
Fibrin glue / hemostatic gel	1	731
Total	159	156 449

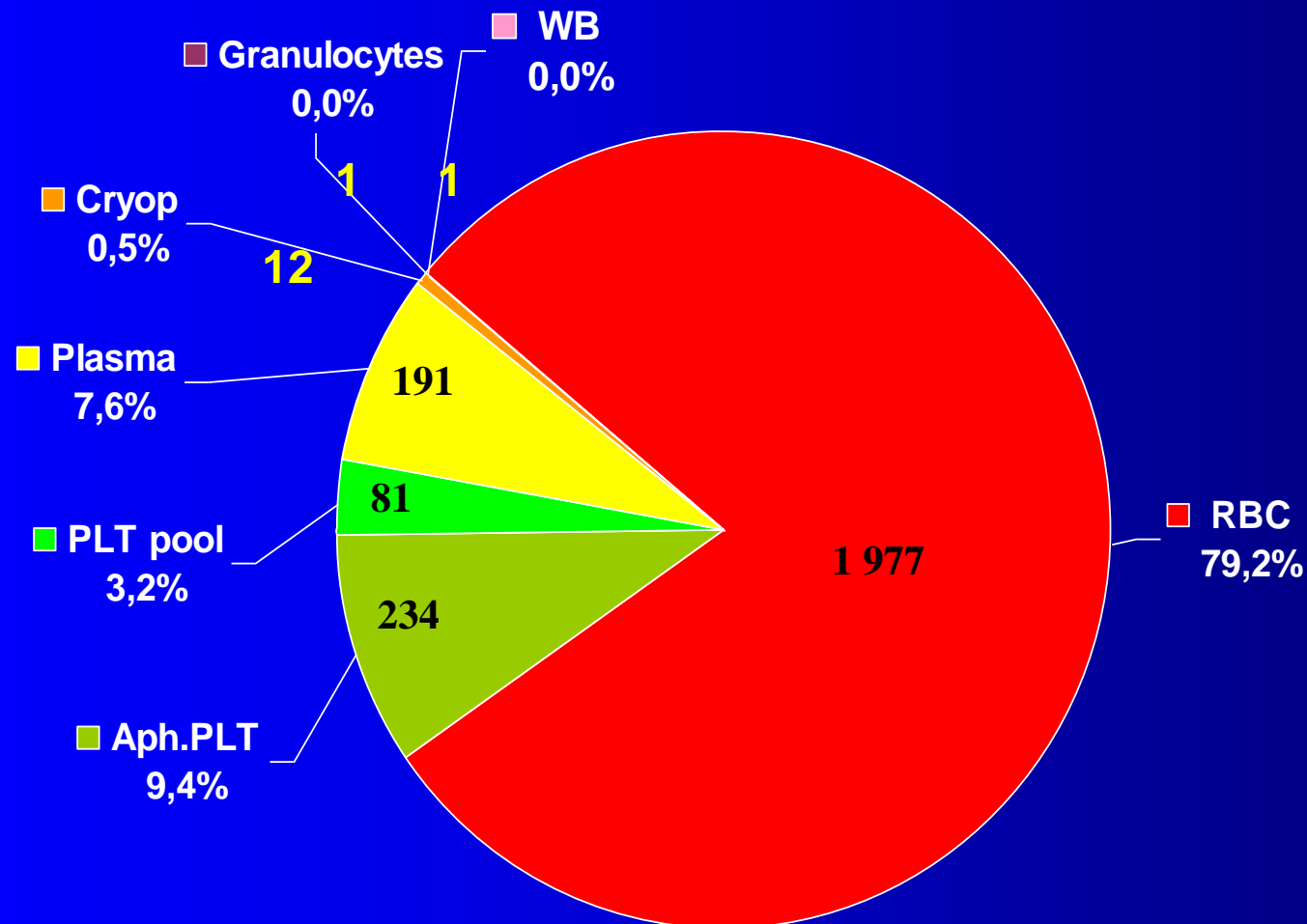
ACCIDENTS

BLOOD COMPONENTS

Accidents Imputability ≥ 2

Type of component associated

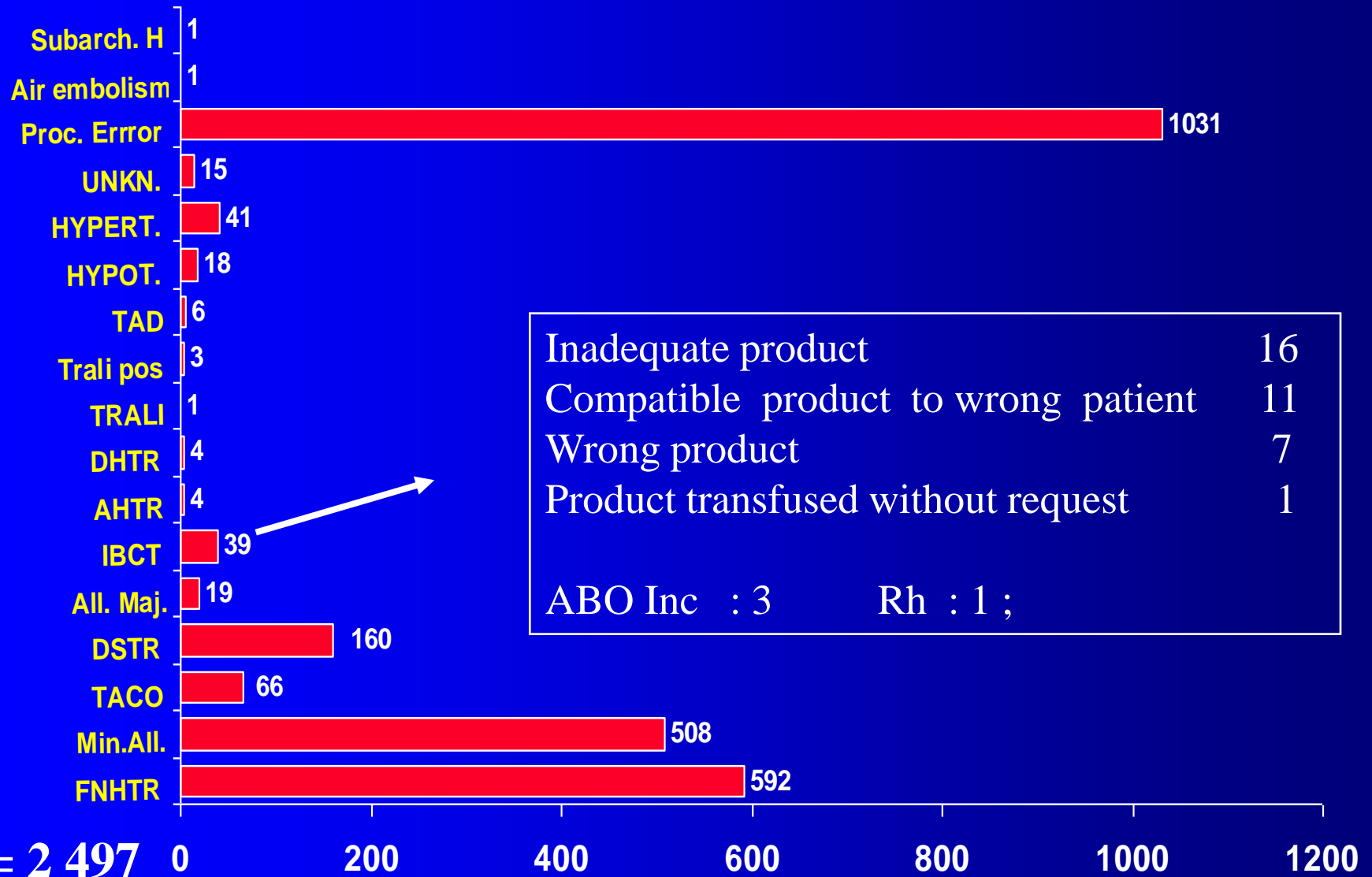
2010



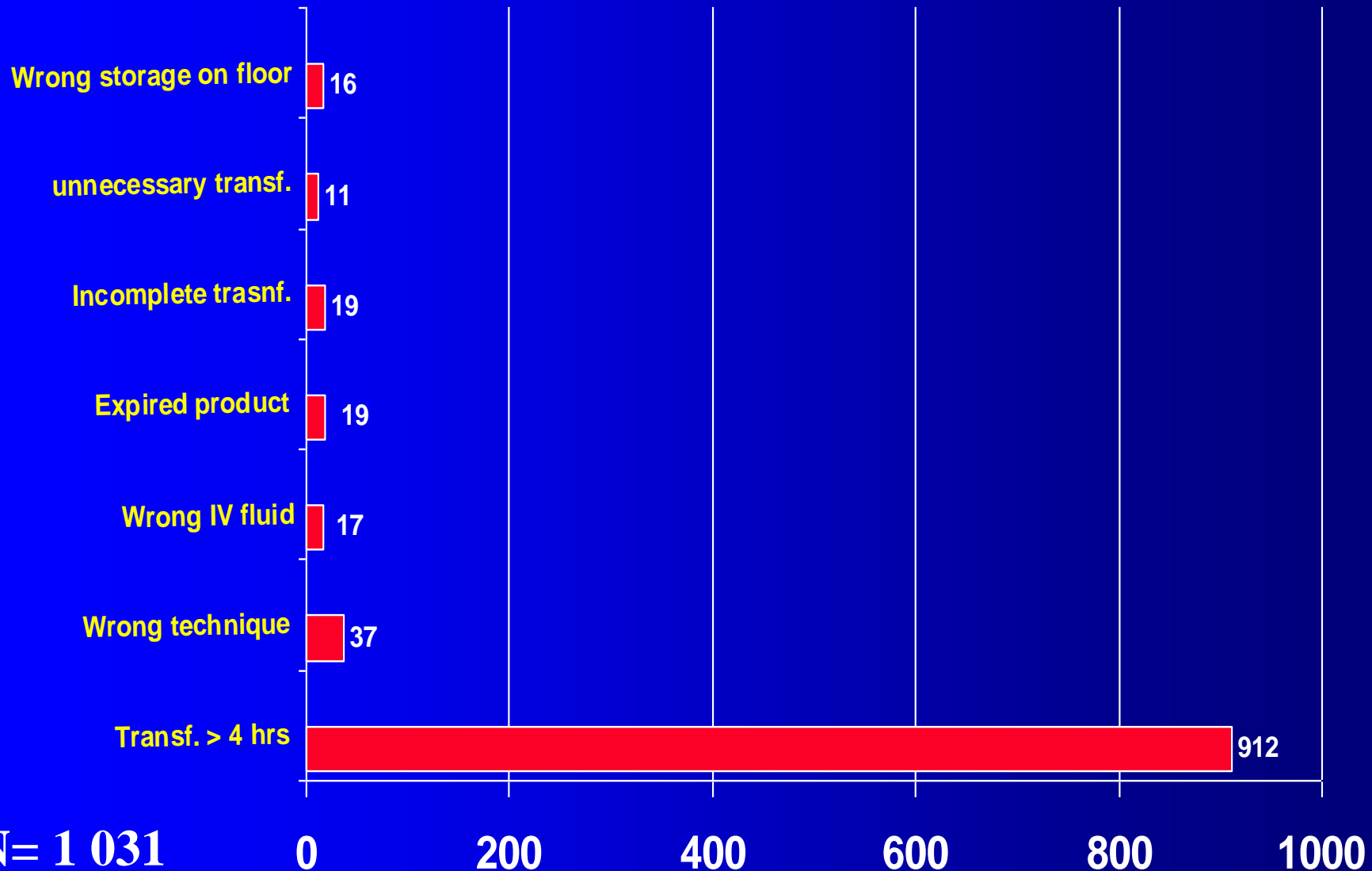
N= 2 497

Accidents Imputability ≥ 2

Type of event 2010

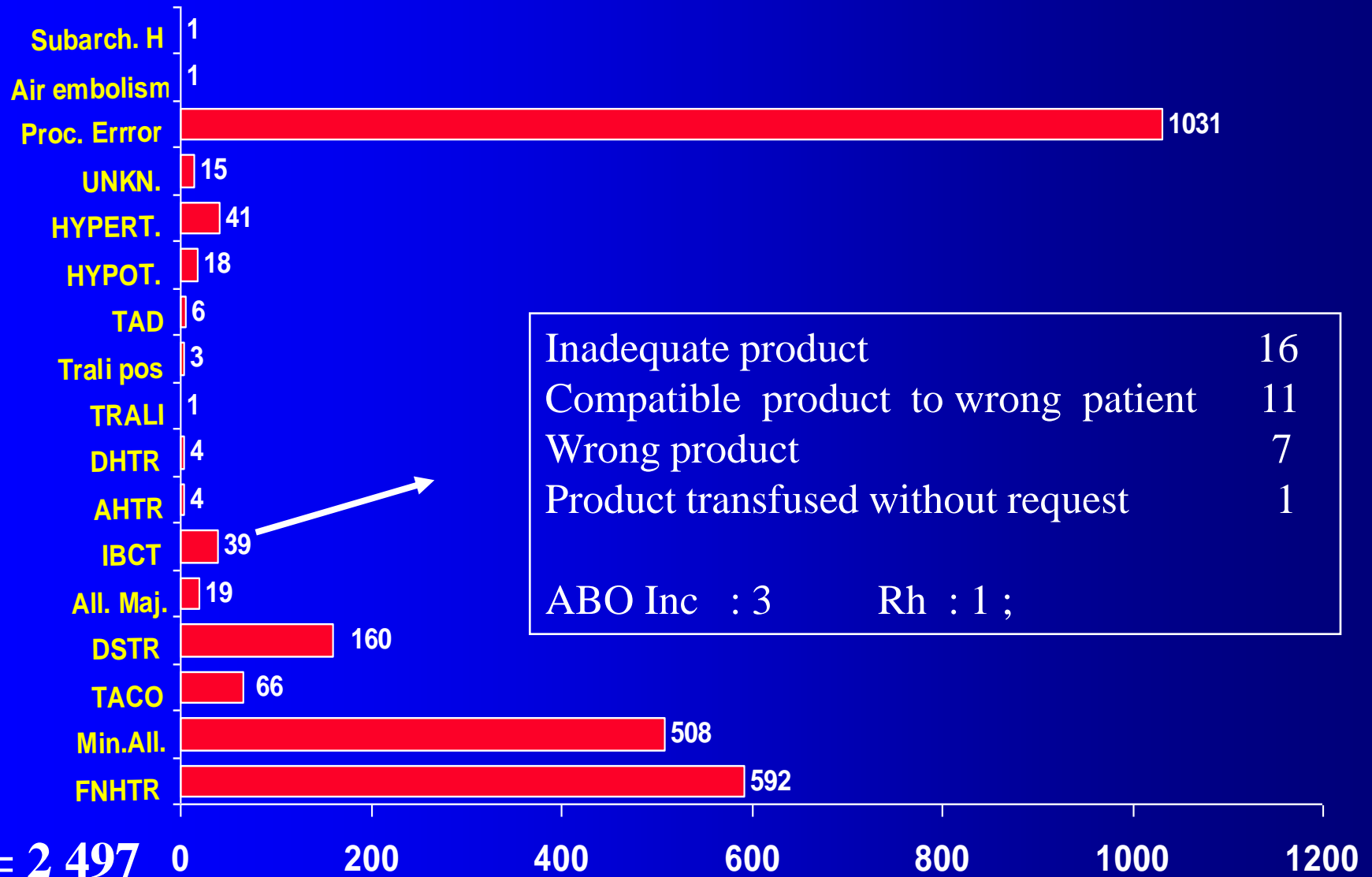


Accidents Imputability ≥ 2 Process errors 2010



Accidents Imputability ≥ 2

Type of event 2010

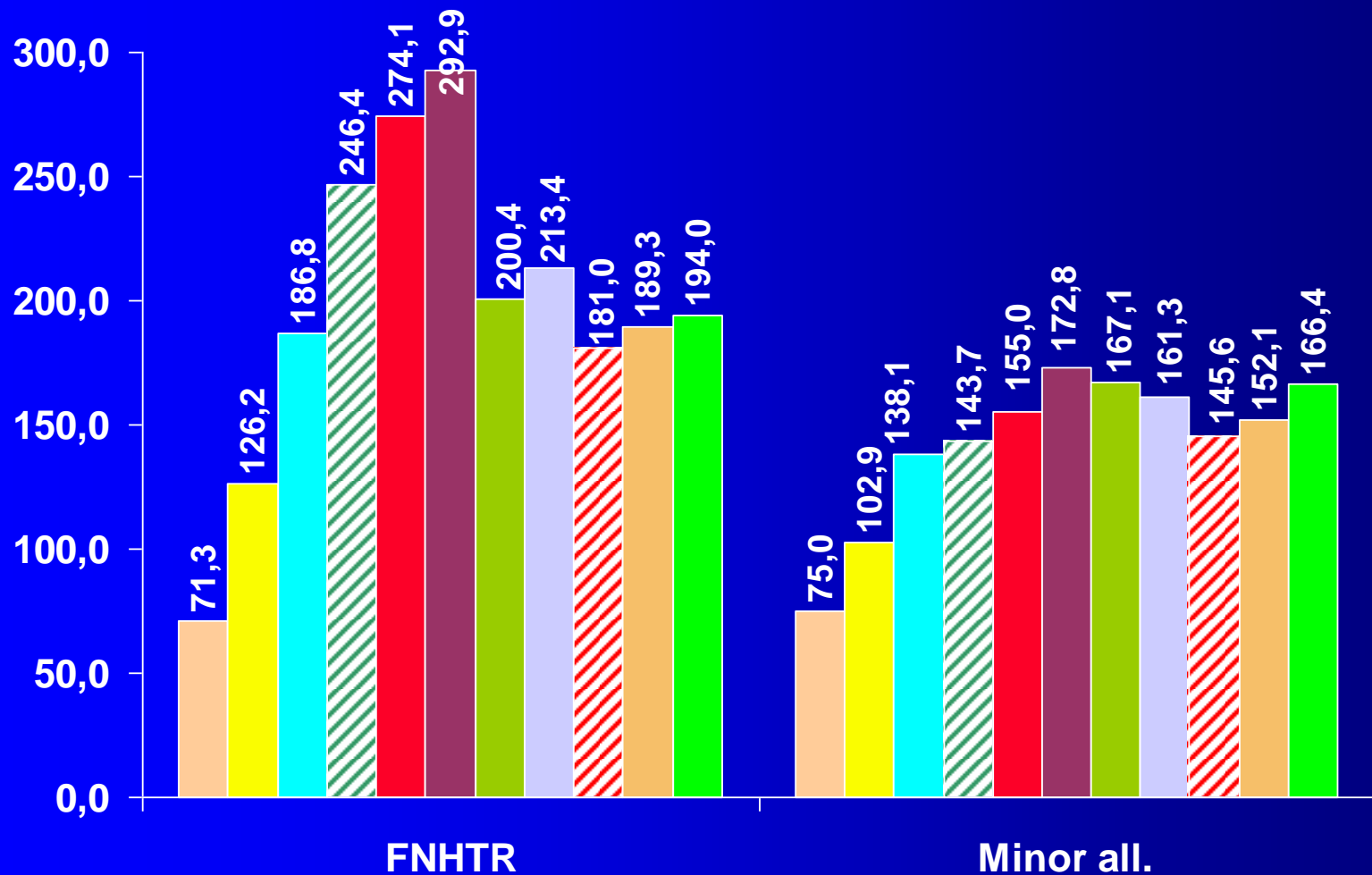


Accidents

BLOOD COMPONENTS

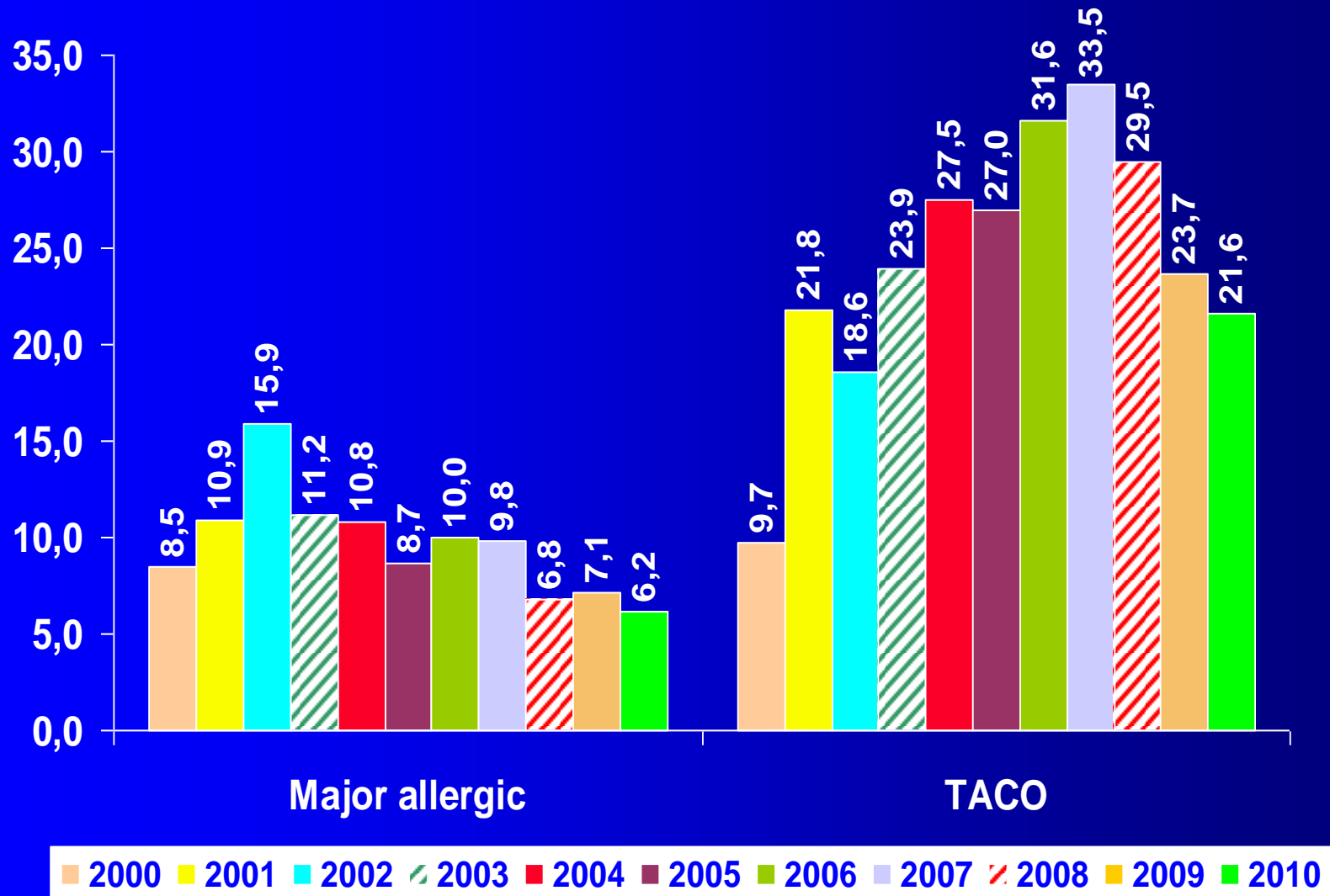
Trends in incidence
2000 - 2010

FNHTR and minor allergic rates



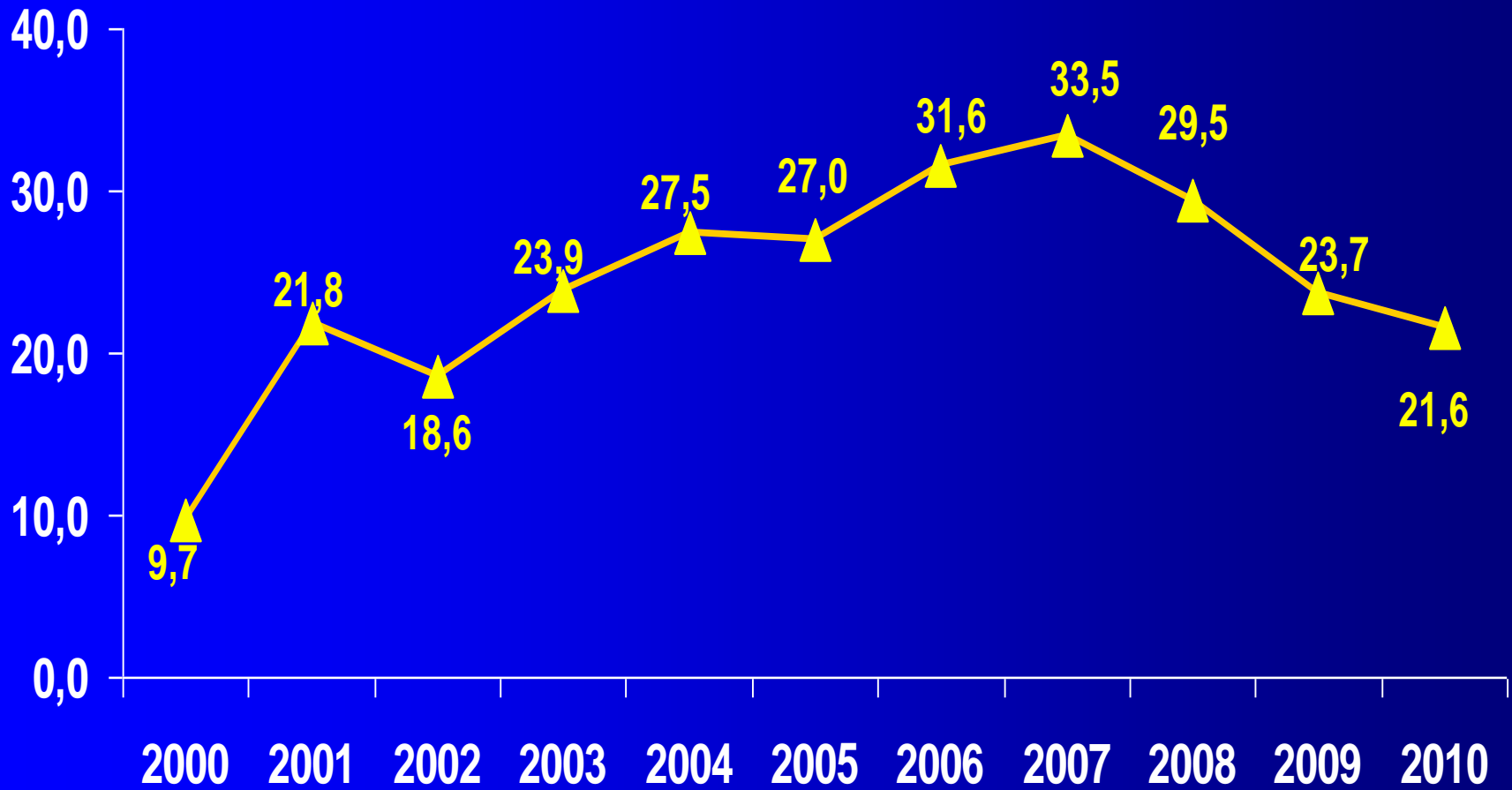
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010

Major allergic and TACO



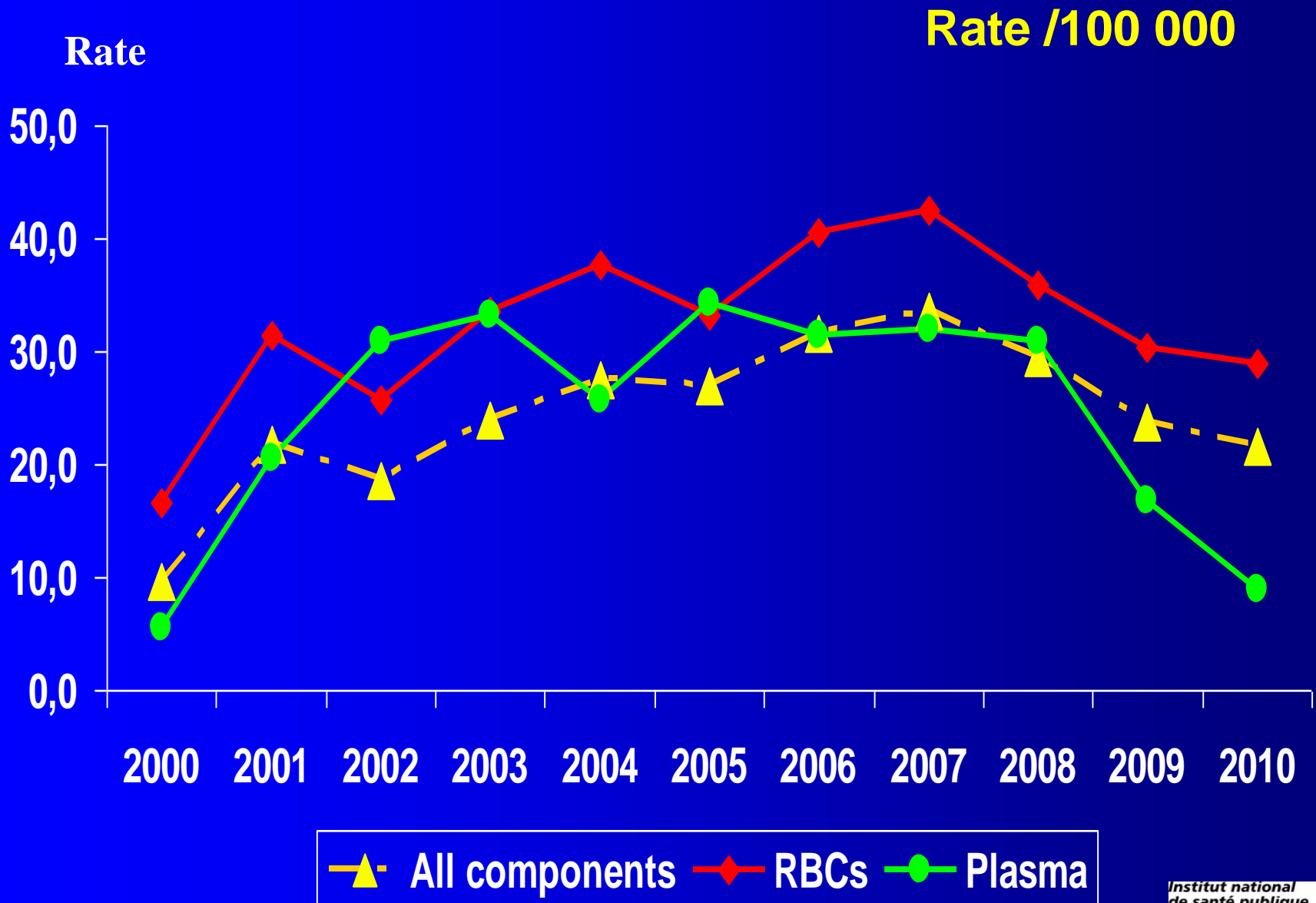
TACO

Rate /100 000

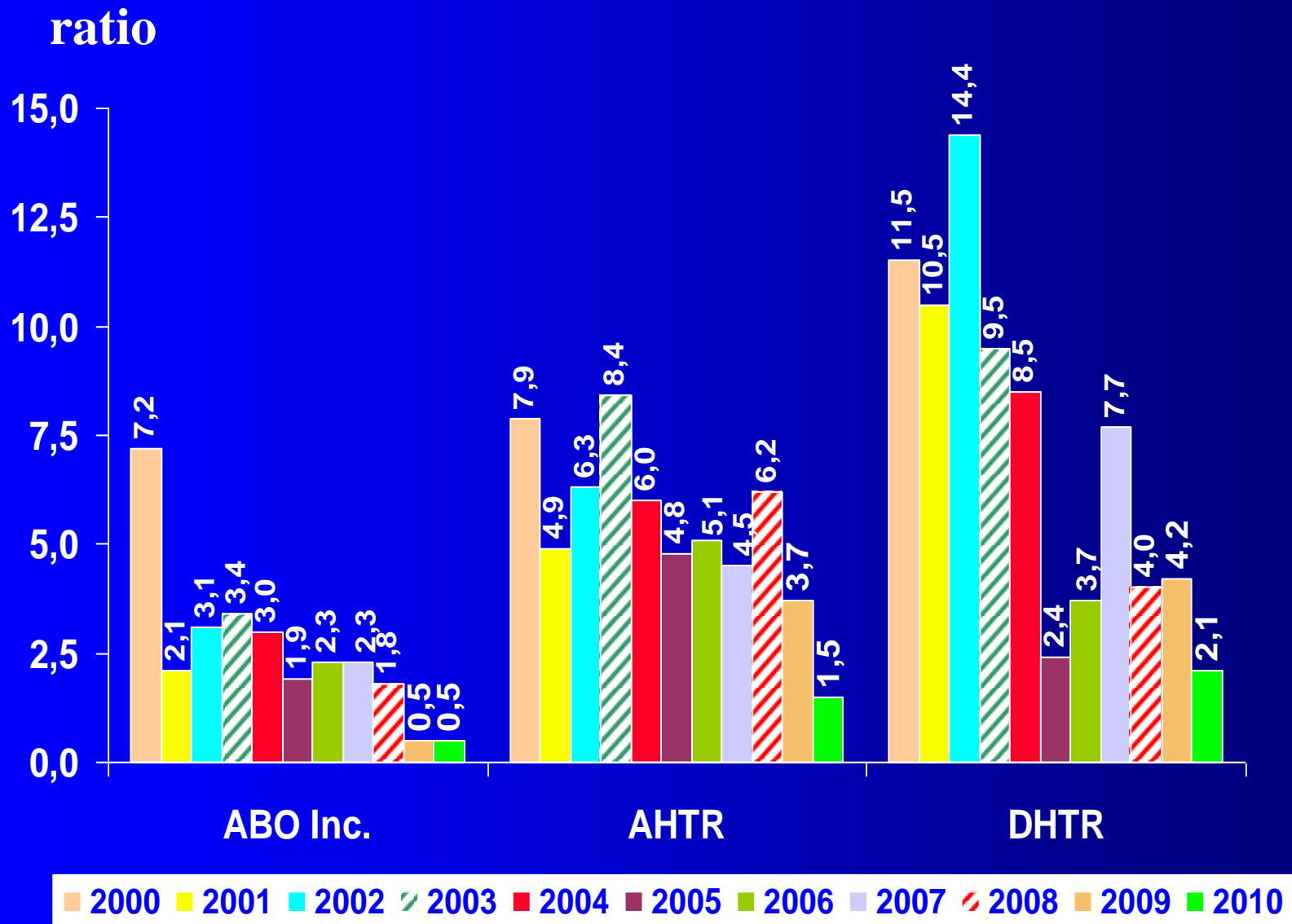


▲ All components

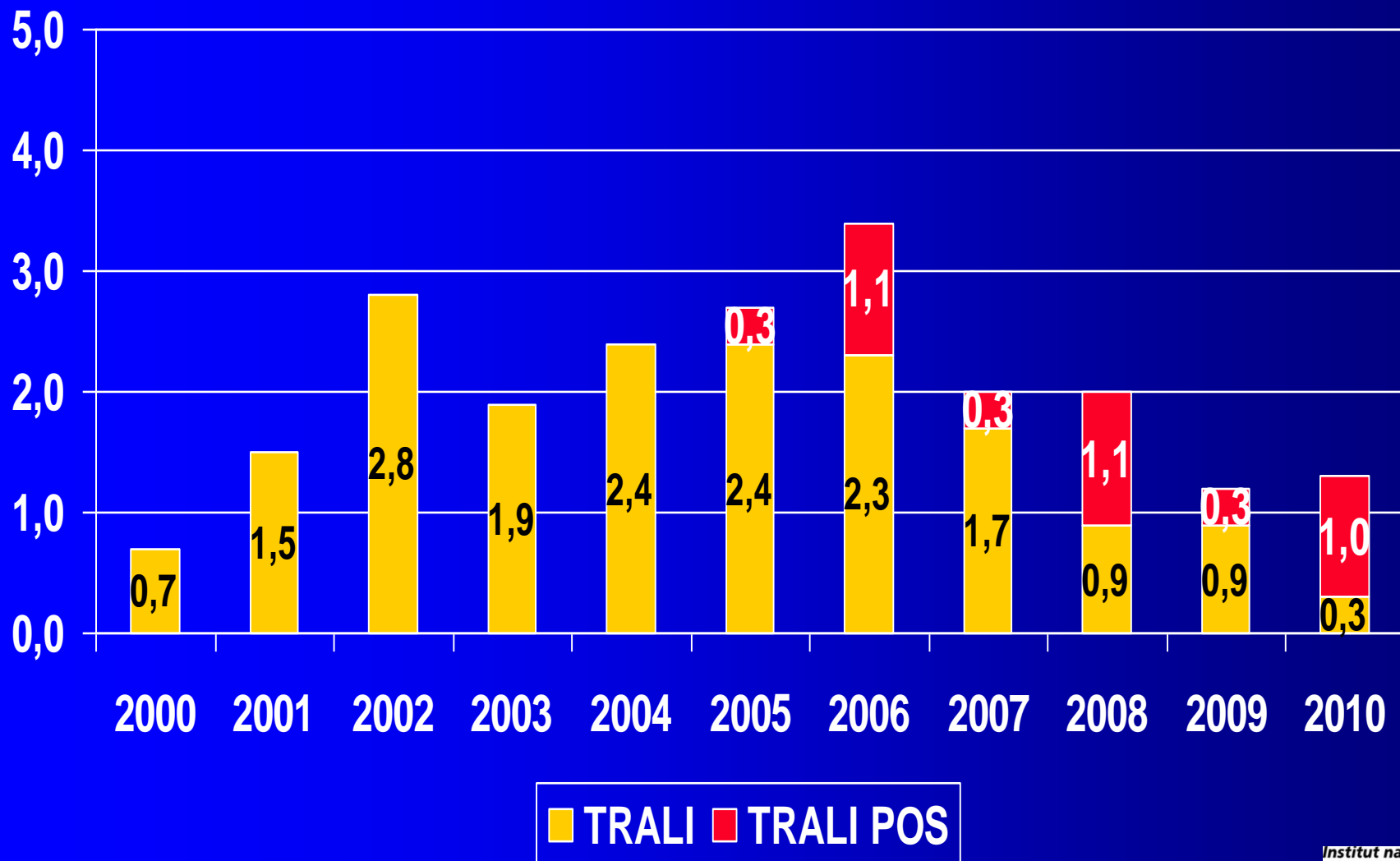
TACO



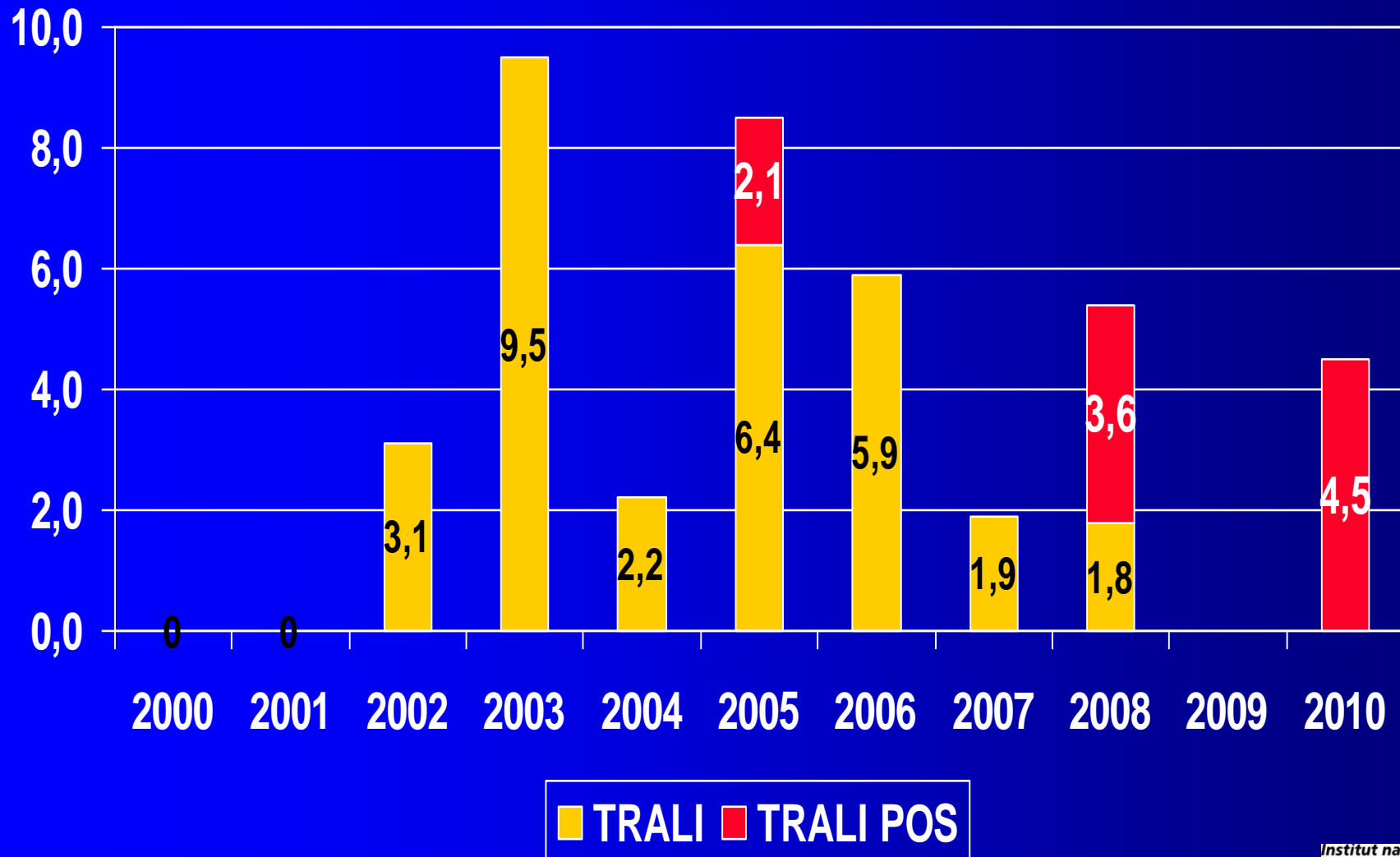
ABO Inc., AHTR, DHTR RBC



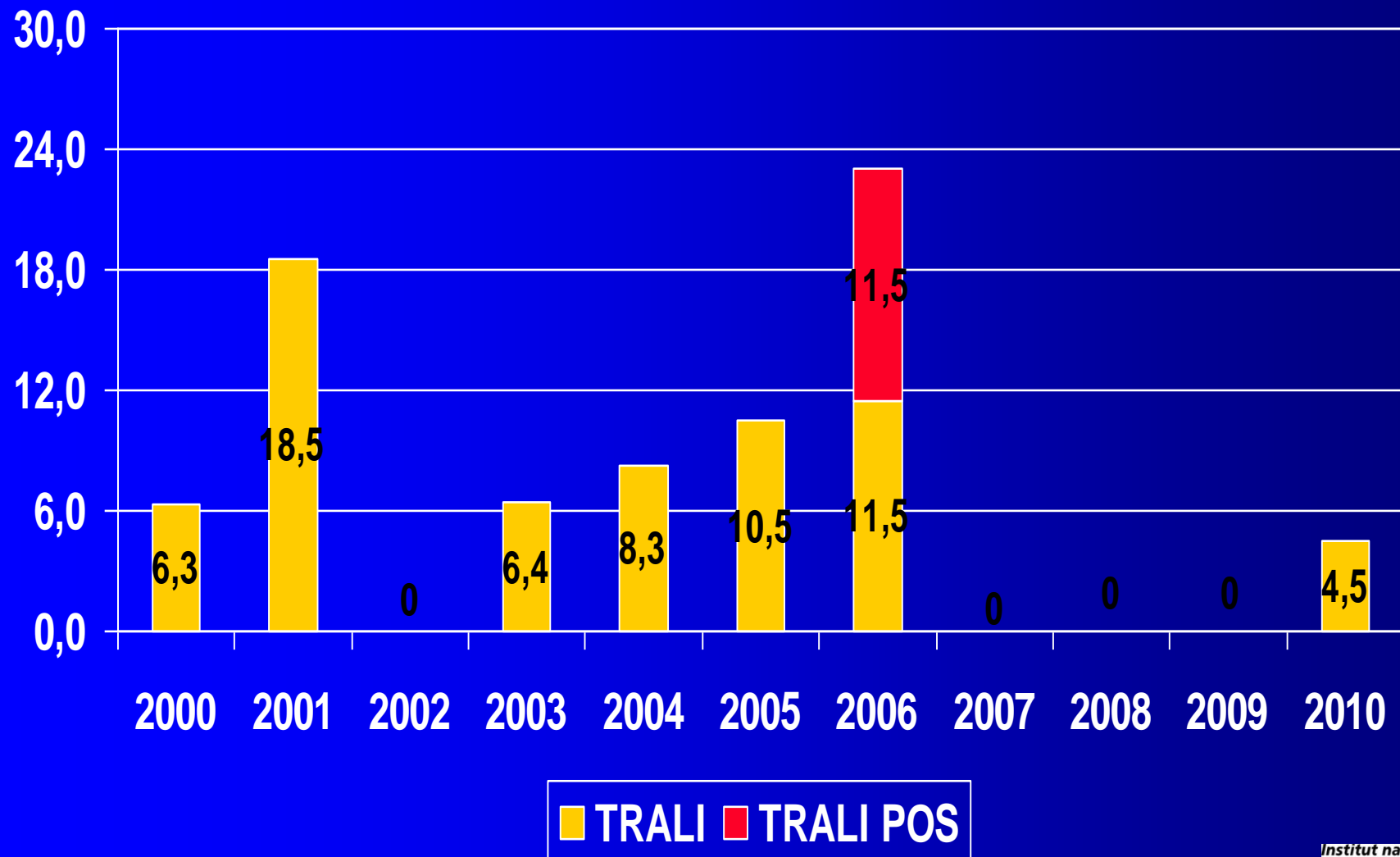
TRALI and Possible TRALI Ratio /100 000 (all products)



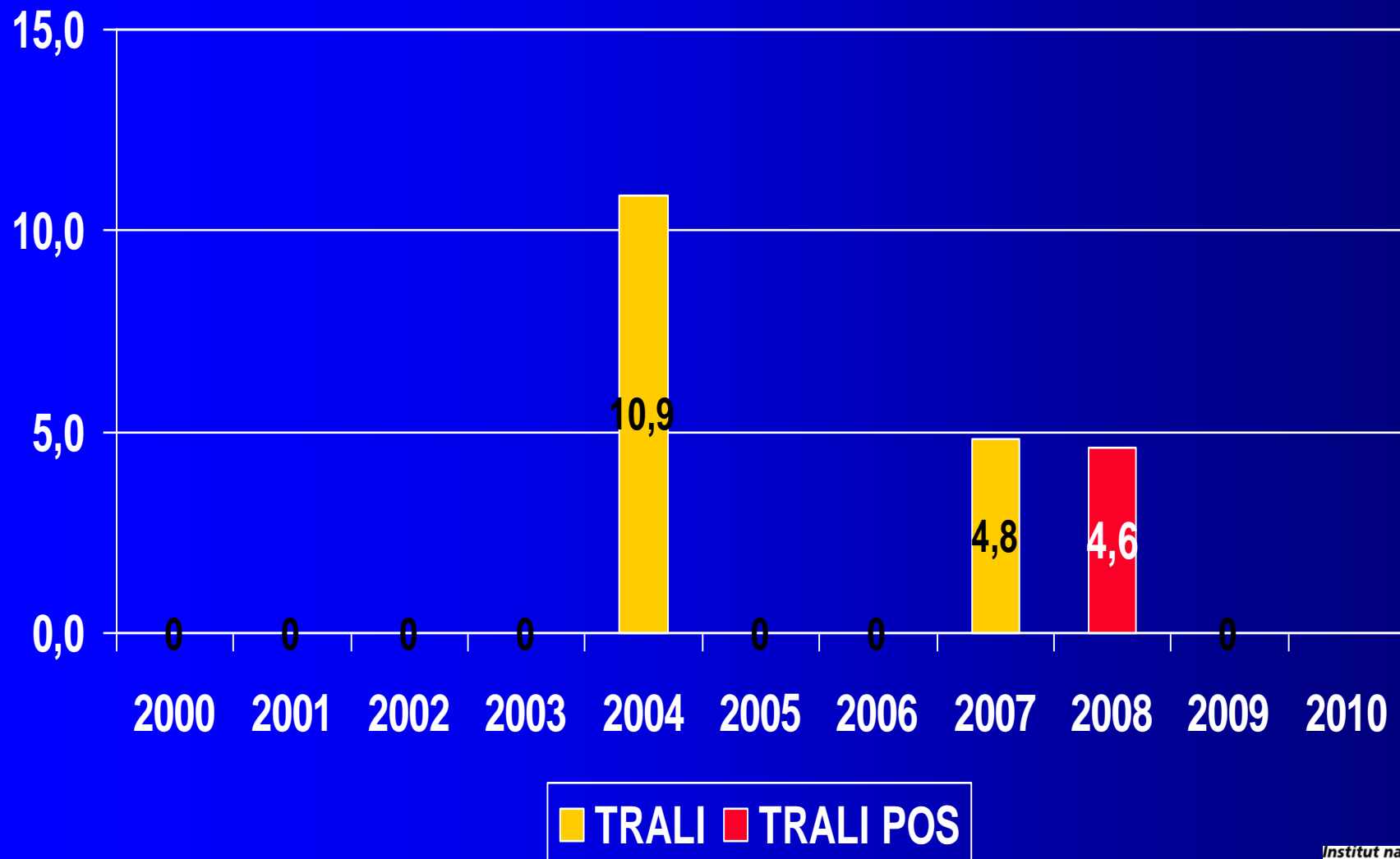
TRALI and Possible TRALI Ratio /100 000 (Plasma)



TRALI and Possible TRALI Ratio /100 000 (PLT pools)

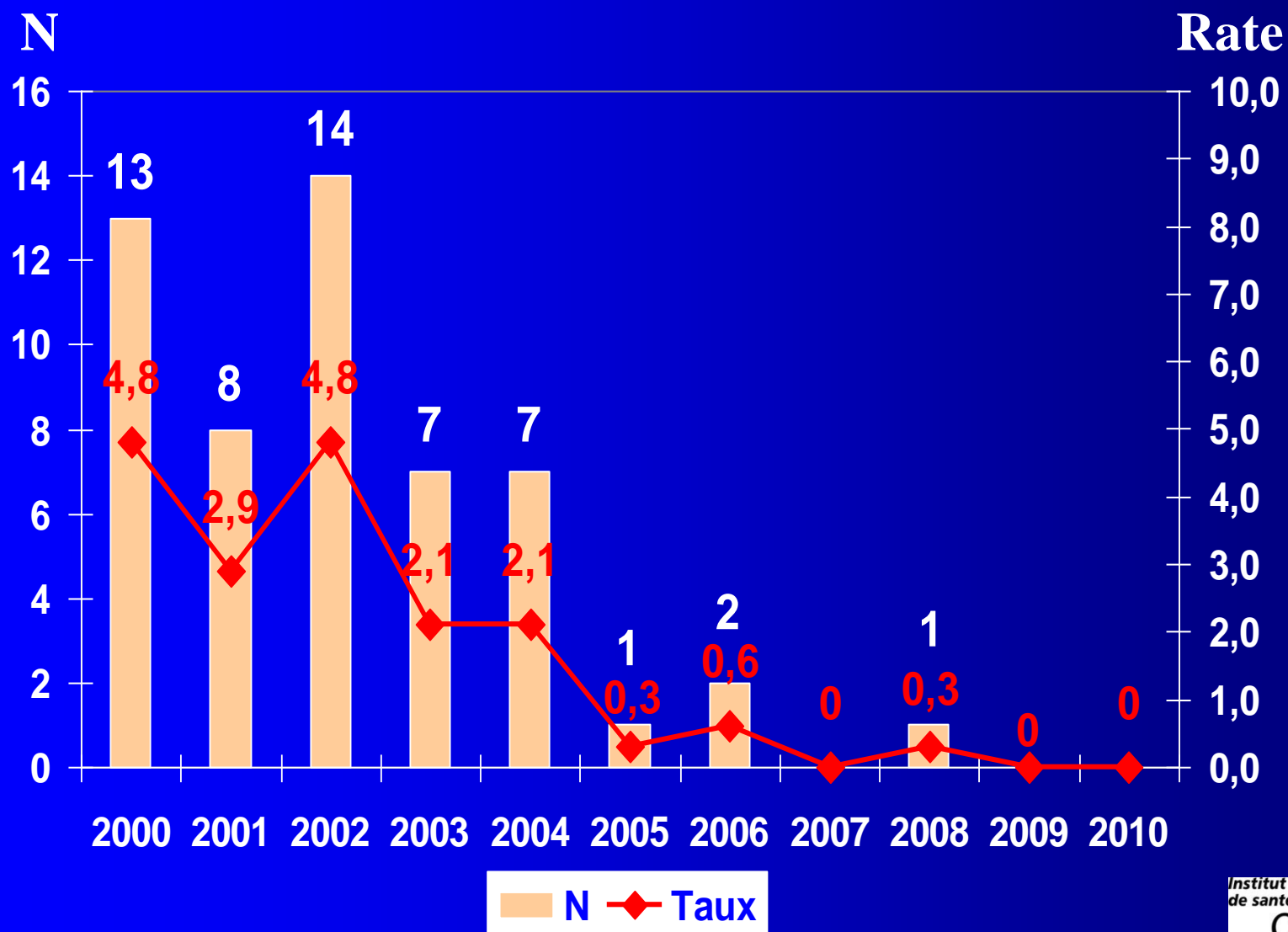


TRALI and Possible TRALI Ratio /100 000 (Aph. PLT)



Bacterial infections

All products



Serious ATR

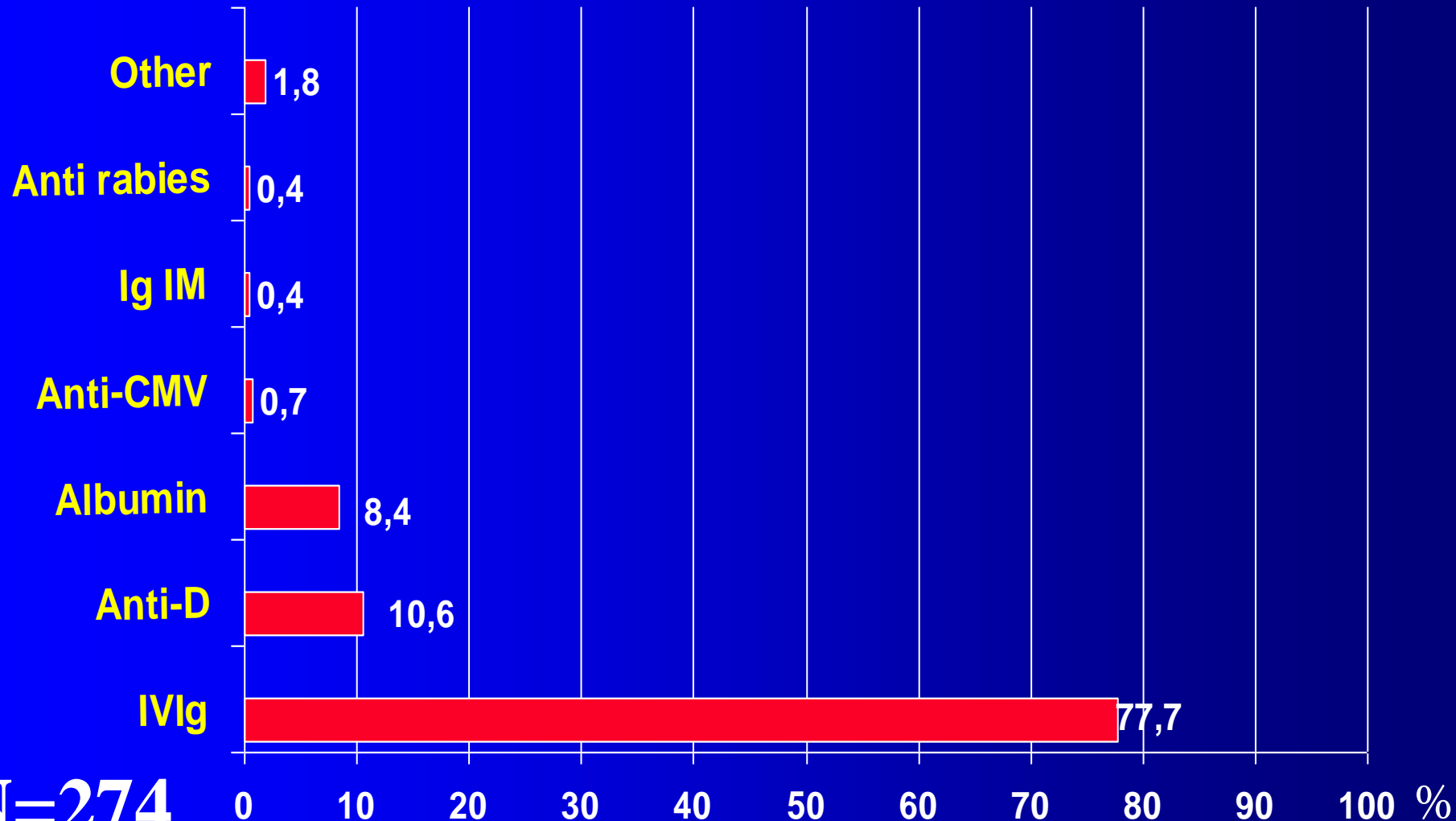
Blood components 2010

	/100 000 units
TACO	21.6
Major allergic reaction	6.2
Immediate hemolytic reaction	1.5
TRALI – TRALI possible	1.3
Bacterial infection	0.0

ACCIDENTS

PLASMA DERIVATIVES

Accidents imputability ≥ 2 Plasma derivatives 2010



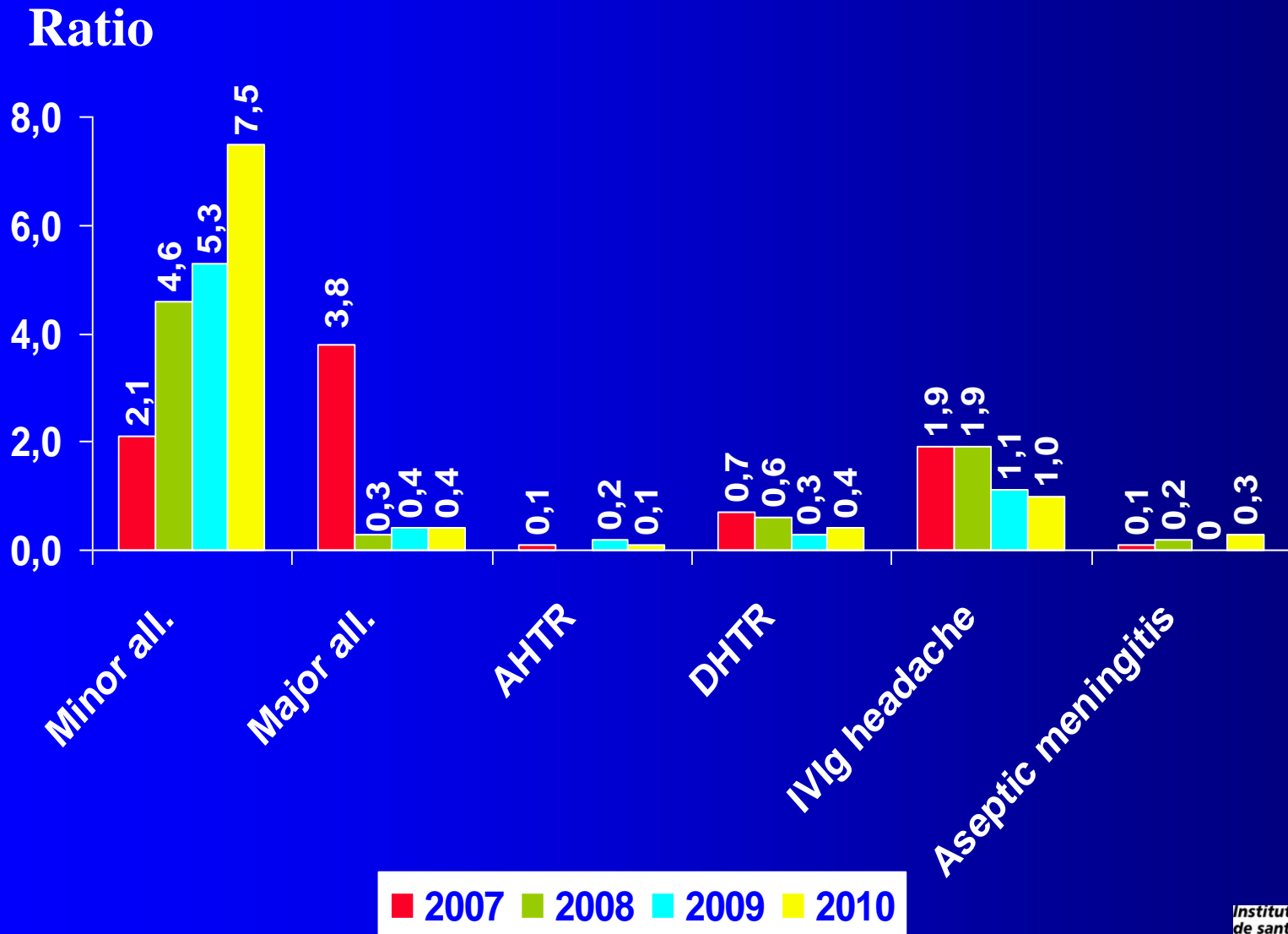
Diagnostics (plasma deriv) – 2010

	IVIg		Ig anti-D		Albumin		Other Ig *		Total	
	N	%	N	%	N	%	N	%	N**	%
FNHTR	45	21.1	3	10.3	4	17.4			53	19.3
Minor allergic Reaction	101	47.4	4	13.8	4	17.4			111	40.5
Major allergic Reaction	5	2.3							5	1.8
AHTR	1	0.5	1	3.4					2	0.7
DHTR	5	2.3							5	1.8
TACO	2	0.9							2	0.7
Wrong product infused	7	3.3	1	3.4	3	13.0	1	25.0	12	4.4
TAD	1	0.5			1	4.3			2	0.7
Hypertension	9	4.2							10	3.6
Hypotension	1	0.5							1	0.4
Aseptic meningitis	4	1.9							4	1.5
Post-IgIV headache	14	6.6					2	50.0	16	5.8
DSTR	2	0.9	2	6.9					4	1.5
IVIg intolerance	6	2.8							6	2.2
Atypical pain	2	0.9							2	0.7
Unknown	5	2.3							5	1.8
Process error	14	6.6	18	62.1	11	47.8	2	50.0	45	16.4
Total	213	100,0	29	100,0	23	100,0	4	100,0	274	100,0

* Ig Anti-CMV, Ig Anti-rabies, Ig SC./ ** includes Fact VIII & hemostatic gel not shown

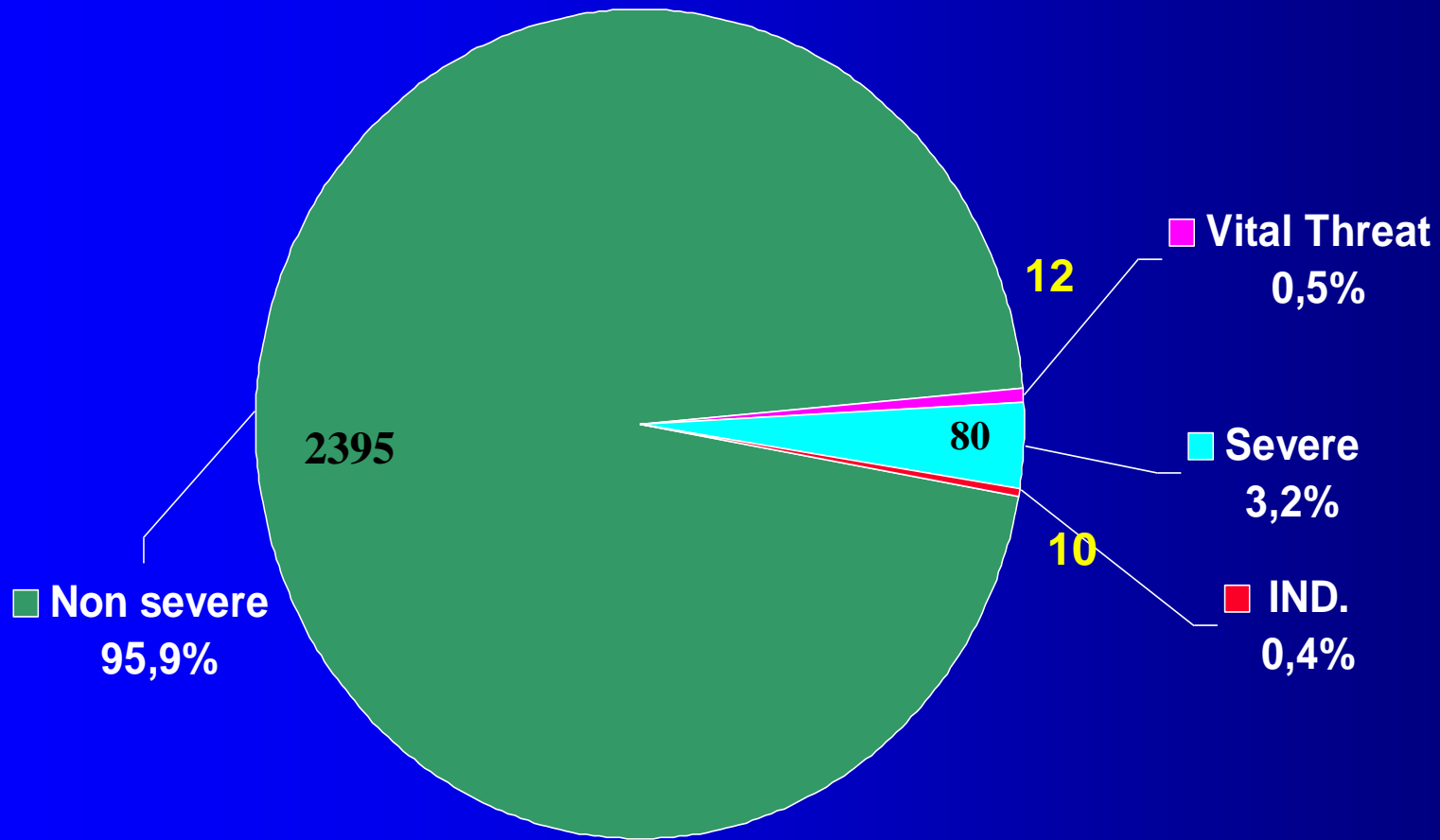
Incidence of accidents related to IgIV

Ratio /100 000 (ALL IVIg)



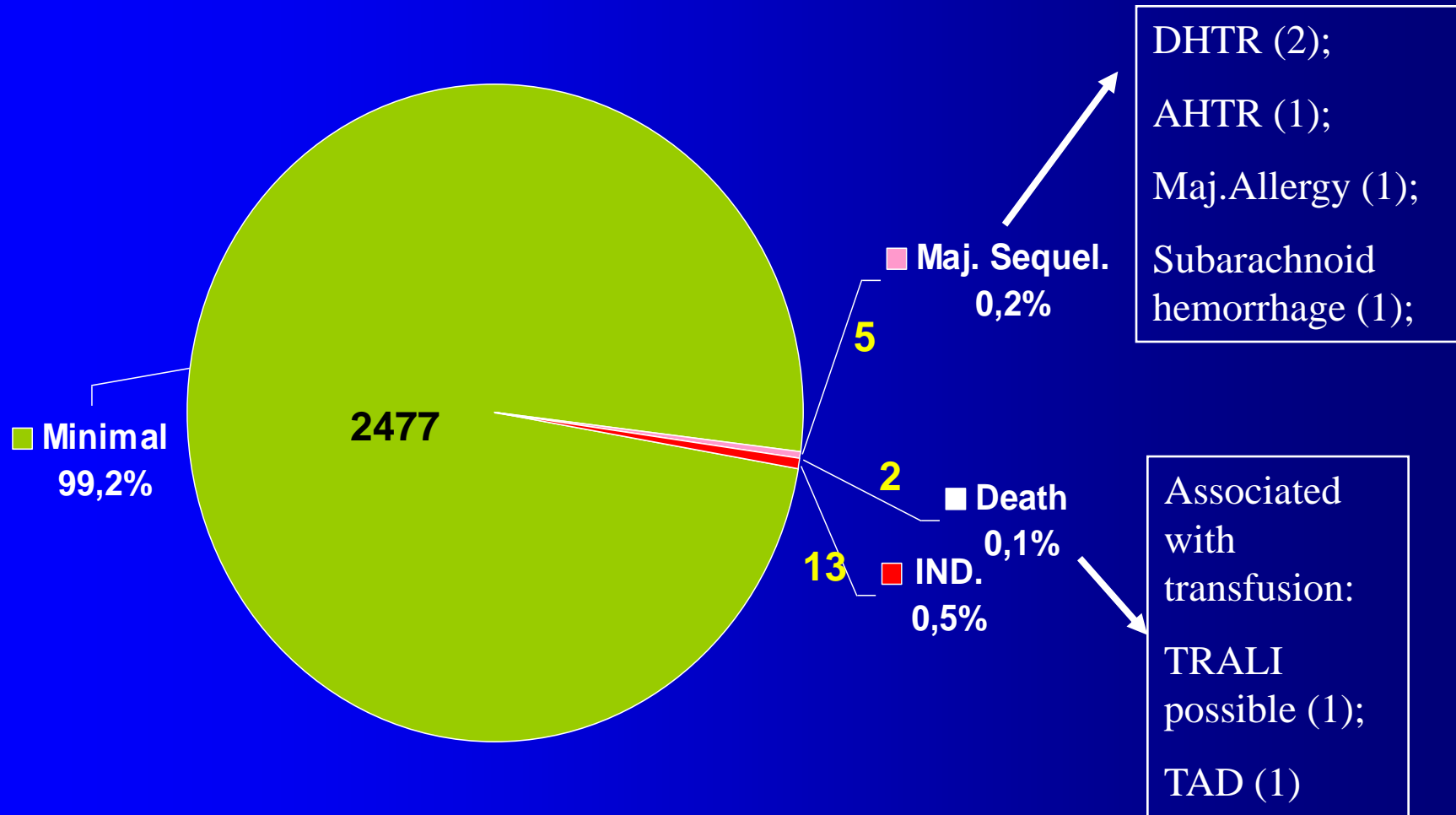
Consequences

Accidents Imputability ≥ 2 Severity 2010



N= 2 497

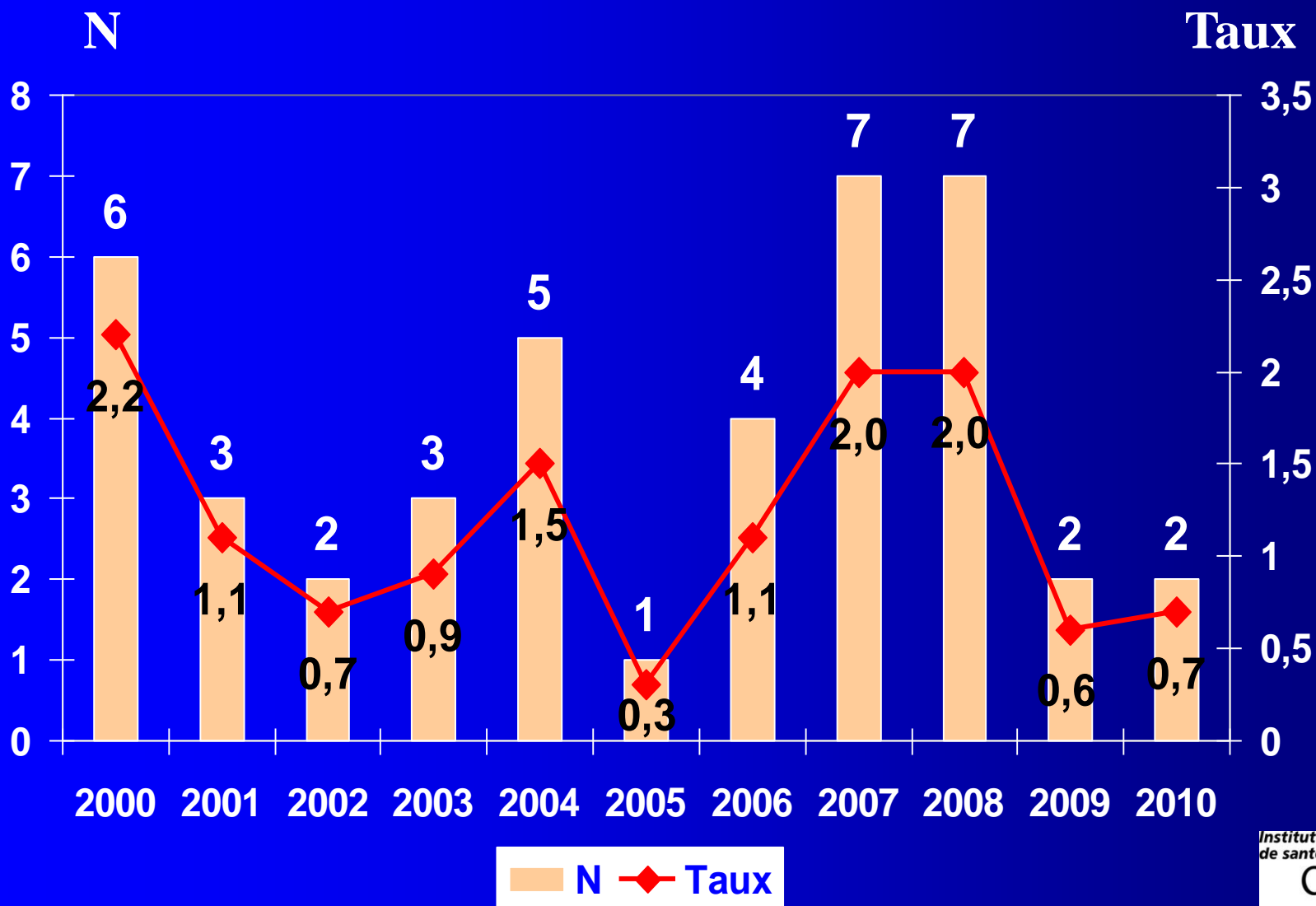
Accidents Imputability ≥ 2 Consequences 2010



N= 2 497

Deaths 2000 – 2010

Frequency and incidence / 100 000



Limits

- **Completeness** : Decrease number of participants centers recently.
- **Sensibility** : QHS is a voluntary surveillance system subject to under recognition and underreporting (problems are mitigated by TSO).
- **Specificity** : Difficulties in establishing the diagnosis and the effect of transfusion –underlying conditions of the patients, available information's...
- **Timelines** : Long delays before final validation.
- **Denominator** : number and characteristics of recipients are not included in Québec's system.

CONCLUSION

- ➔ The QHS has been effective in collecting data on adverse transfusion events.
- ➔ Data were useful for identifying priorities for prevention and to evaluate preventive measures.
- ➔ The incidence of serious reactions (TRALI, TACO, major allergy, bacterial infection, death) seems to decrease.

Acknowledgements

- **Québec Health Ministry**
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- **Network of Hospital Transfusion
Safety Officers**
- **Québec blood bank directors**