



Nationwide adoption of pathogen inactivation for platelet concentrates in Switzerland

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Swiss Blood Transfusion Service

13 Regional Blood Transfusion Services (RBTS)

Population of
7'600'000

Transfusions performed
in ~200 hospitals



Units transfused in 2011:

- ~ 310'000 RBC
- ~ 60'000 Plasma
- ~ 30'000 Plt concentrates

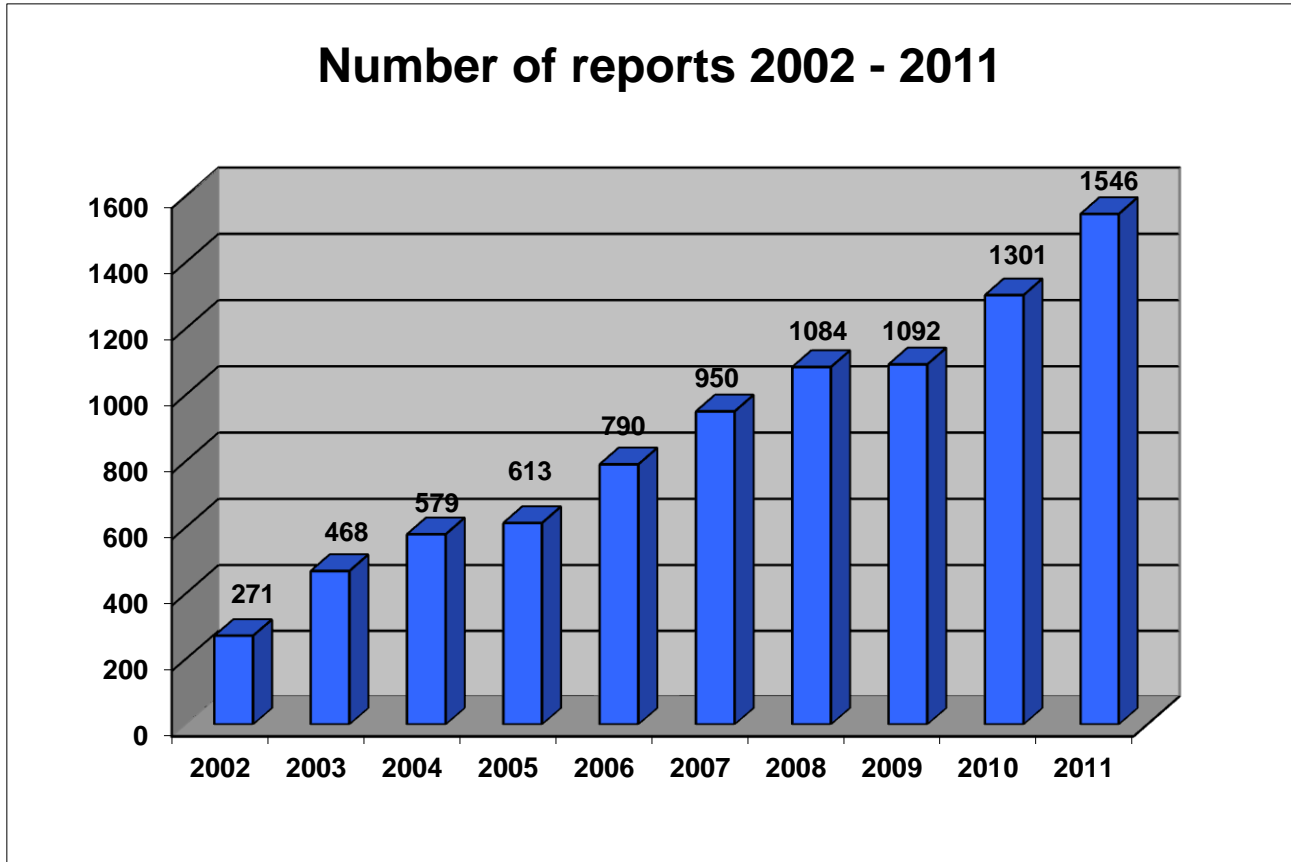


Swiss Haemovigilance System

- Reporting is mandatory since 2002
- **All** reactions and events are reported
- Haemovigilance officers report to Swissmedic



Current Haemovigilance data

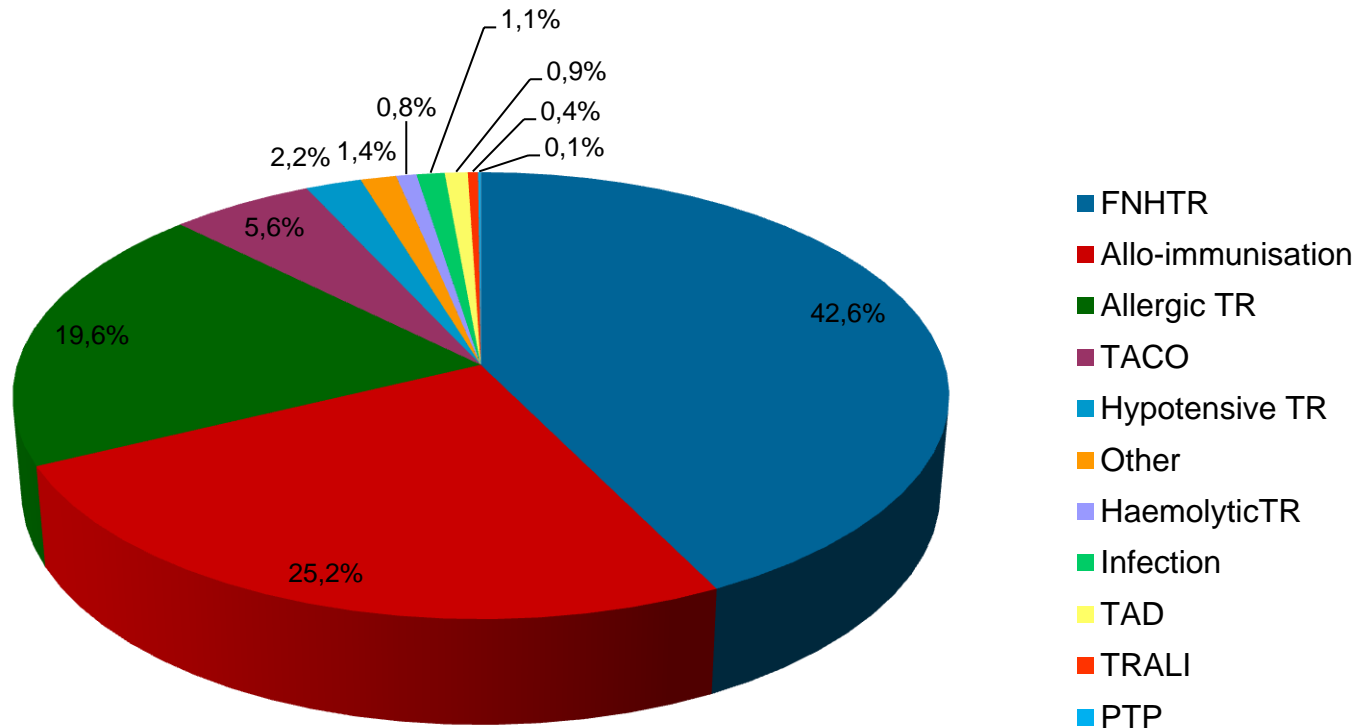


Reporting rate 2011: 3.9 reports per 1000 transfusions



Current Haemovigilance data

TR 2011 by classification and frequency





Latest achievement

Nationwide implementation of the INTERCEPT® Pathogen Inactivation (PI) procedure for all platelet concentrates in Switzerland in the course of 2011



Morbidity and Mortality due to bacterial contamination of platelet concentrates in Switzerland (2005-2009)

- 15 febrile/septic reactions (including 3 fatal)
- 130'000 transfused products (5 years)

Morbidity ~1:8'000

Mortality ~1:40'000 (~ one per 1.6 Y)

Without bacterial detection and > 90% aphaeresis PLT units



Options

Reduced storage time

- 4 instead of 5 days (e.g. Germany) → **missing ~50%!!**

Bacterial Screening:

- Several systems available in Europe
- BacT/ALERT® (Biomérieux) assumed as Gold Standard

Pathogen inactivation

- Only one system currently has marketing authorisation in Switzerland (Intercept ®)



Bacterial Screening

Pro

- Reduces risk
- Simple to perform
- Recognised technology
- Moderate costs

Con

- Sensitivity/specificity problem (up to ~50% false negatives)
- Issued as negative to date
 - Detected positive later
- Reduces bacterial risk only
- Loss of PLT due to sampling



Pathogen Inactivation

Pro

- Effective for majority of bacteria, viruses, protozoa including emerging & non-tested pathogens
- Transfusion reactions ↓
- γ -irradiation superfluous
- *Stop CMV screening! & others?*
- *Relax donor exclusions? (travel,...)*

Con

- Long term safety?
- Loss of ca. 10-15% PLT and modestly of function
- Costs (1,4 Mio \$ /QALY?!)* (but compare: 2,7 Mio \$ / QALY for additional Hep B/C & HIV – NAT)
- Monopoly of company

- Custer B et al, Transfusion 2010;50:2461-2473
- Davidson T et al, Transfusion 2011;51:421-429



Decision

Joint decision in 2009 by Swissmedic and Swiss Red Cross Blood Transfusion Service to implement the INTERCEPT® Pathogen Inactivation (PI) procedure for all platelet concentrates in Switzerland

Nationwide implementation in 2011



Implementation

- 2010 planning and pre-validation phase
- A specific manufacturing authorisation issued to each RBTS by Swissmedic after individual validation
- Begin routine production in the three pilot centres in January 2011 (covering approx. 50% of PC production in Switzerland), the remaining 10 centres followed in the course of 2011
- Implementation completed by end 2011, now 100% supply with PI-PC



Expectations

- No more septic transfusion reactions after PC-transfusion
- Decrease in the number and severity of PC-related transfusion reactions
- An increase in platelet collection (up to ~ 15%)
- Possibly compliance problems with the clinicians

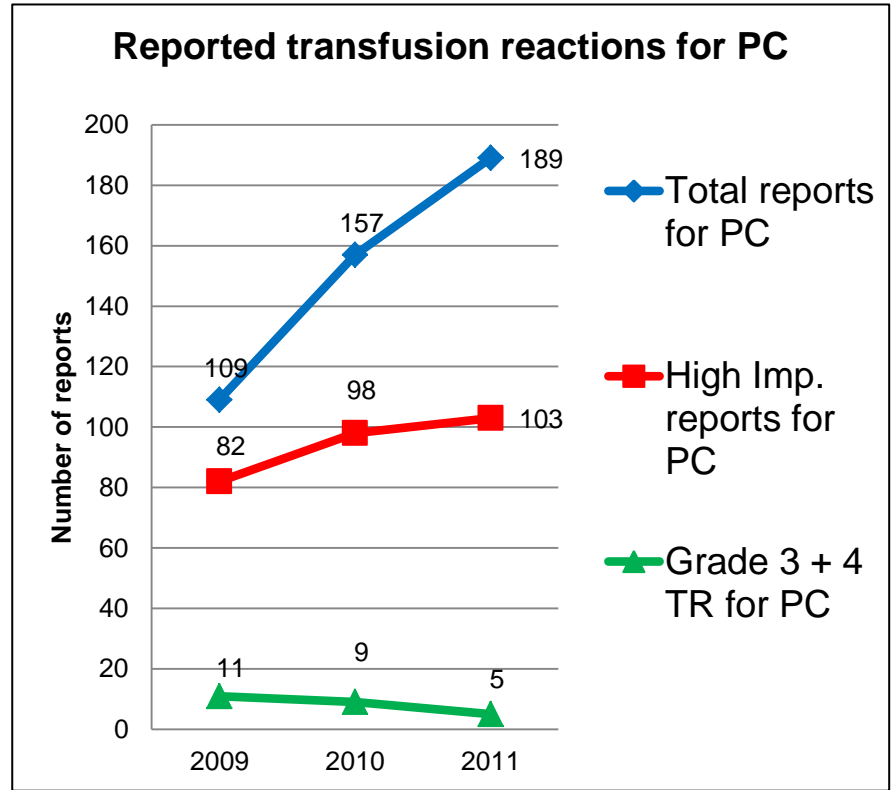
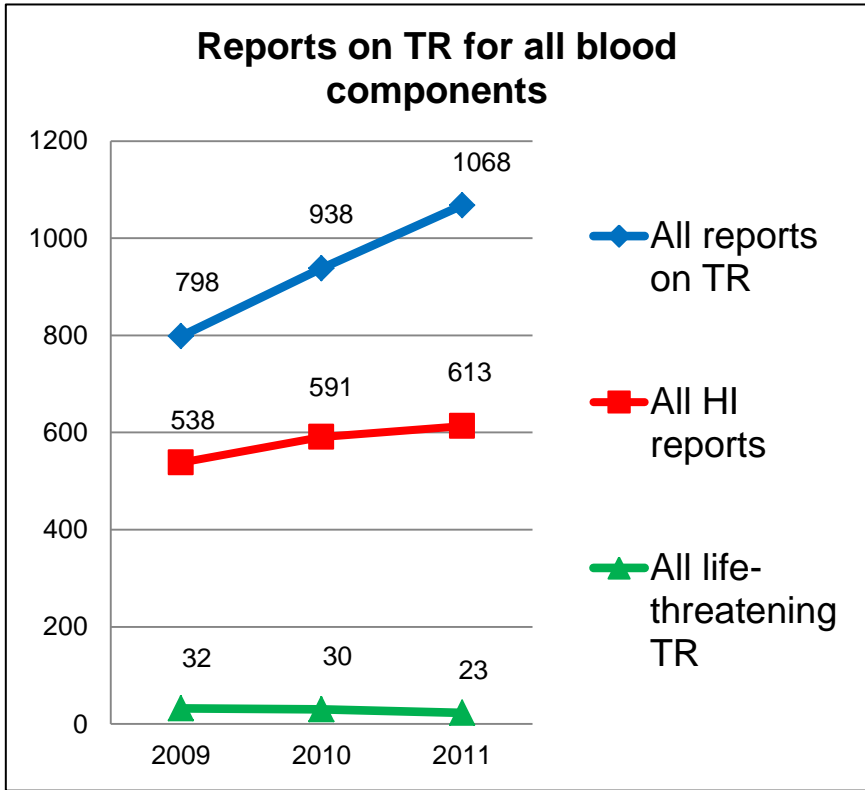


Observations 2011– Transfusion data

- ~ 80% PCs pathogen inactivated, ~ 20 % conventional PCs
- 33'000 PCs transfused, increase of ~ 10.5%, due to:
 - General increase in patients needing PC transfusions (e.g. stem cell transplant patients, trauma patients, massive transfusions)
 - Precautionary raise of the transfusion trigger (from 5 to 10 G/l) for prophylactic PC transfusions in some clinics
 - PC's transfused more readily in others (PI products considered safer)
 - Possibly lower CCI ► clinical significance??
- Whole blood derived PCs increased from 14 to 23% of all PCs
 - To meet the rising need
 - As contribution to cost reduction

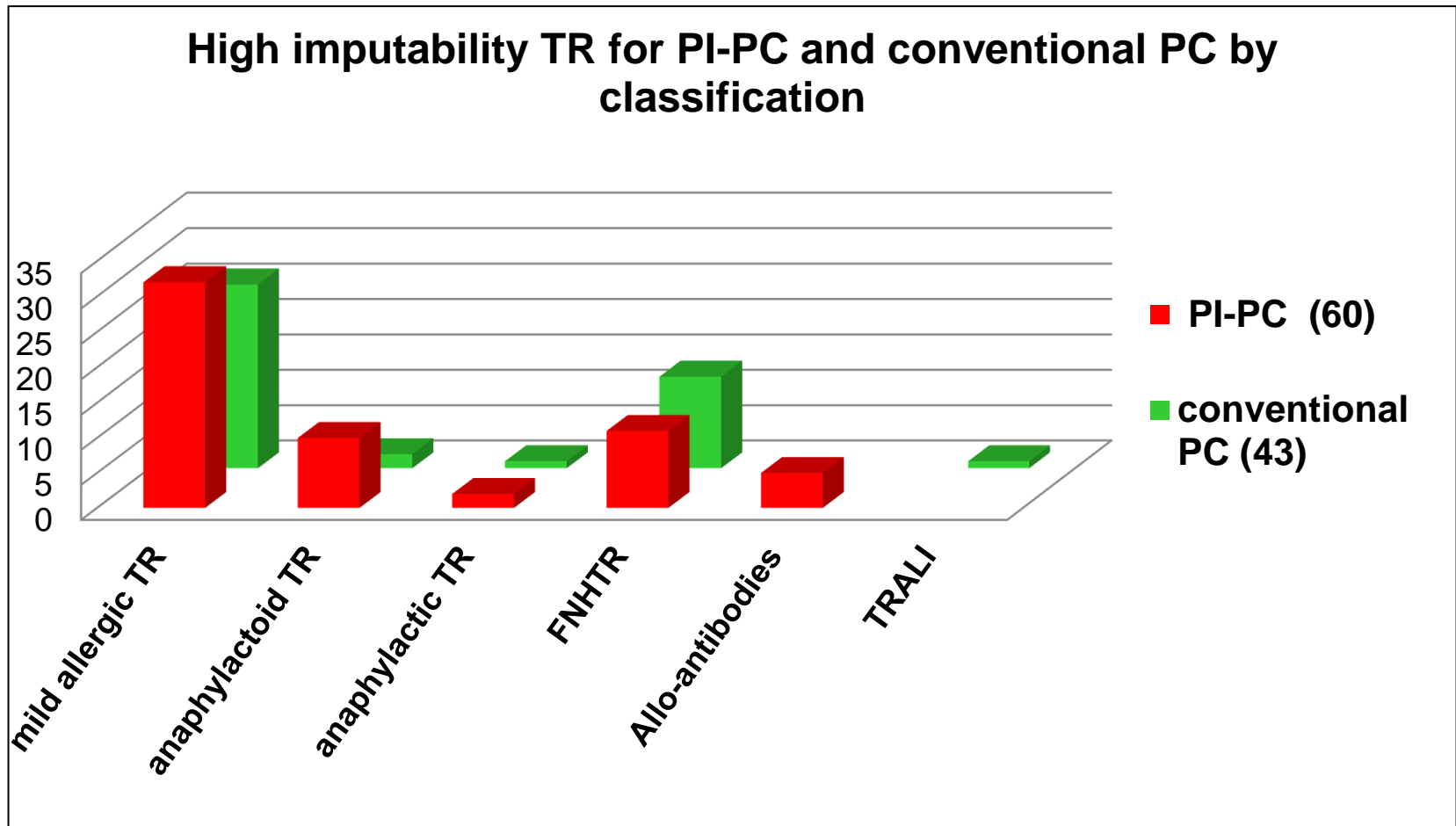


Observations 2011– Haemovigilance





Observations 2011– Haemovigilance





Risk of transfusion for PCs 2011

Transfusion reactions	2011 PI-PC's		2011 conventional PC's		2010 (only conventional PCs)	
	Reports	Risk	Reports	Risk	Reports	Risk
Units transfused	26'454		6'614		29'900	
Risk = 1 reaction per x PC transfusions	Reports	Risk	Reports	Risk	Reports	Risk
All high imputability reactions	60	~1: 440	43	~1:150	98	~1:330
High imputability grade 3 reactions	3	~1:8800	2	~1: 3300	9	~1:3300



Summary

- As expected, no transfusion transmitted bacterial infections were observed after PC transfusions in 2011
- No reports of increased bleeding / clinical inefficiency of PC
- Less than 2/3 of the reported TR occurred after the transfusion of PI-PC (80% of all PCs transfused), whereas the 20% conventional PC's generated more than 30% of all PC-related reports.
- Lower risk for adverse events observed, especially for life threatening reactions (risk reduction from 1:3'300 to 1: 8'800)
- Demand for PC increased by 10.5 %



Conclusion

- PI for platelet concentrates substantially reduces the risk for bacterial TTIs and also for platelet related transfusion reactions in general
- Our findings underline the superior safety profile of pathogen inactivated PCs
- It remains to be seen how this trend towards declining platelet related TRs develops over the next few years when more Haemovigilance data become available

Thank you for your attention





Observations 2011– Transfusion data

Blood components	2009	2010	2011	Difference 2010 - 2011
Apheresis PC	26380	25'876	25'499	- 1.5 %
Whole blood derived PC	3220	7'569	10'969	+ 86 %
Total PC	29'600	29'938	33'068	+ 10.5 %



Transfusion data Switzerland

Blood components	2007	2008	2009	2010	2011
Red cell concentrates	308'470	313'587	311'521	308'670	308'627
FFP (units)	69'800	65'800	70'300	61'500	50'063
Platelet concentrates (products)	22'900	27'600	29'600	29'900	33'068
Total Blood components	401'229	407'079	411'528	400'070	391'758