



# 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

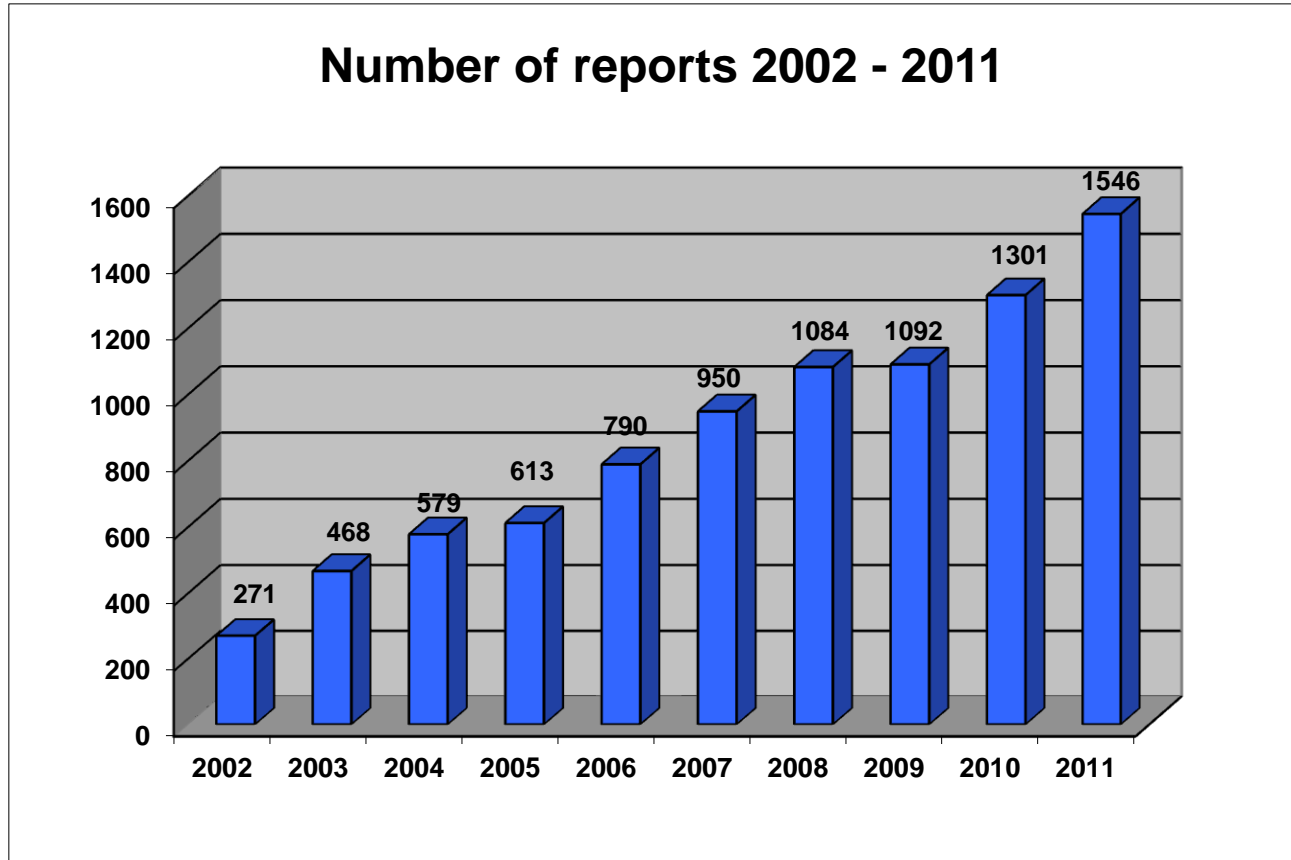


# Swiss Haemovigilance System

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



# Current Haemovigilance data

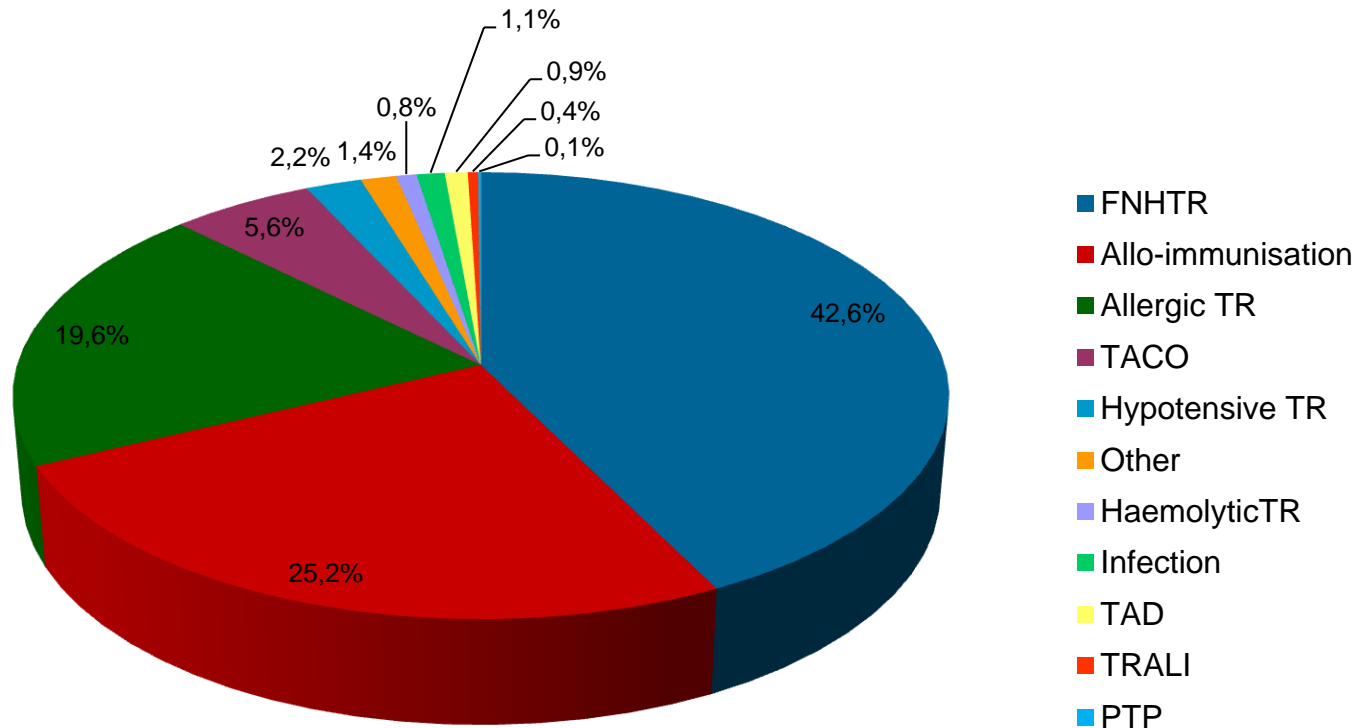


Reporting rate 2011: 3.9 reports per 1000 transfusions



# 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 ↓
- $\gamma$ -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

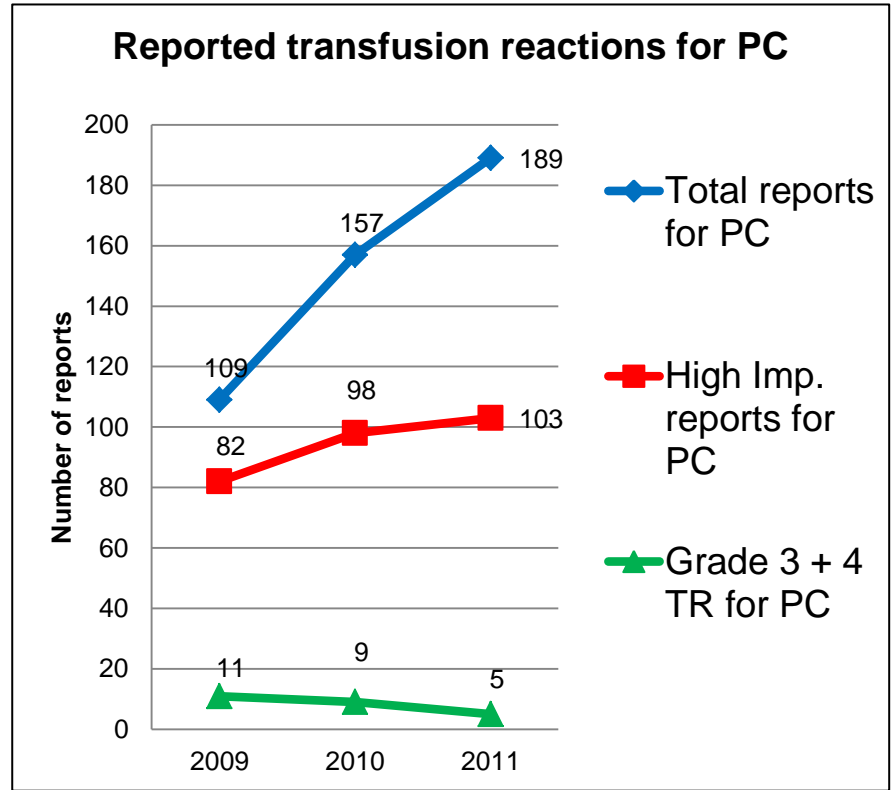
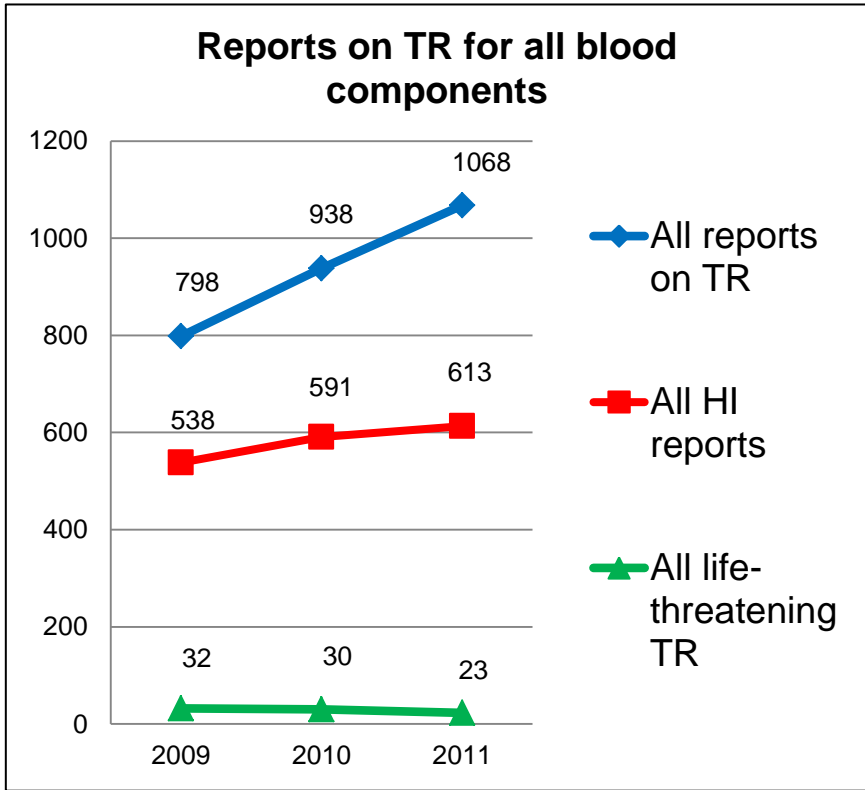


# Observations 2011– Transfusion data

- ~ 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

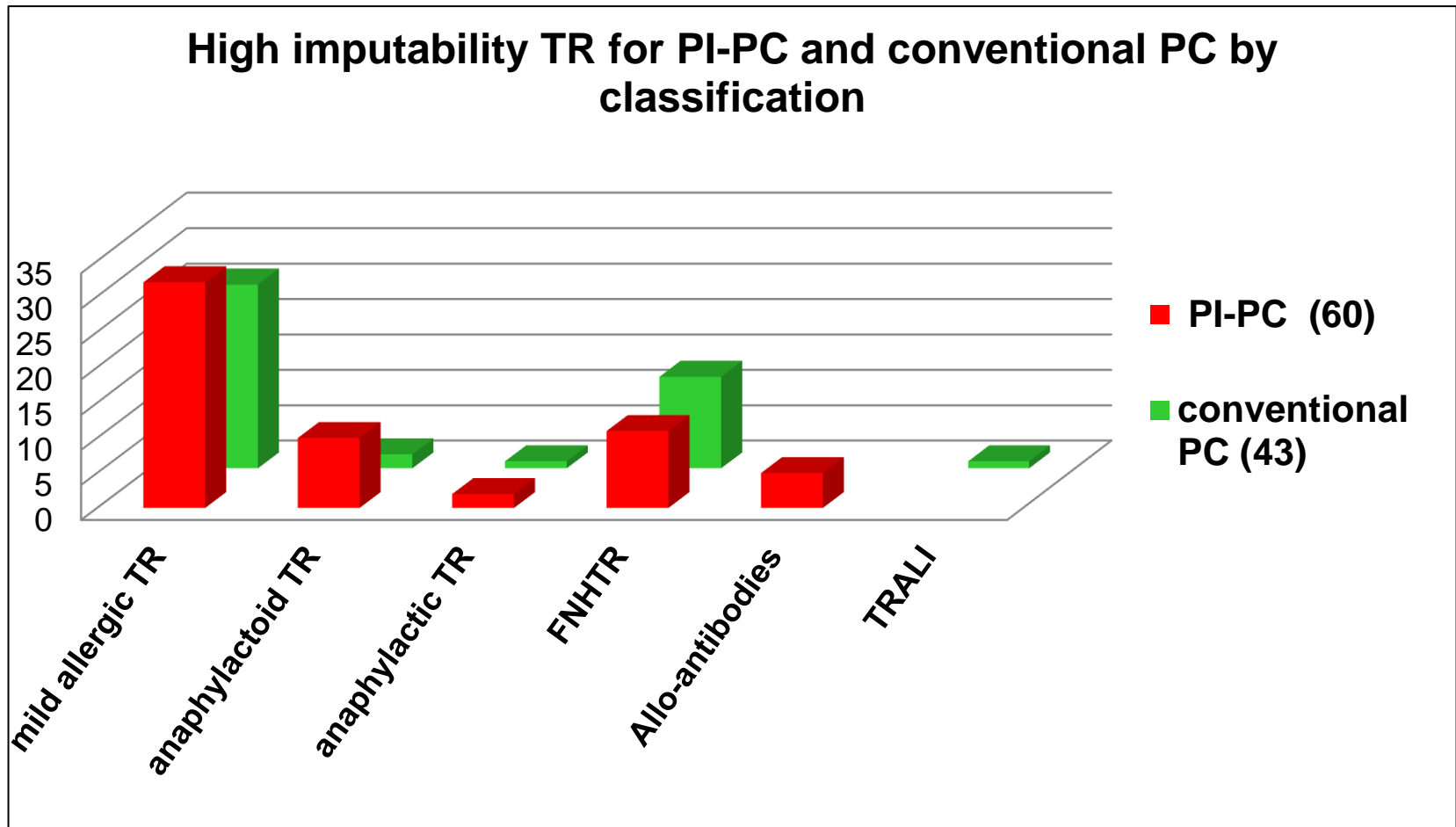


# Observations 2011– Haemovigilance





# 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

<b>Blood components</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>Difference 2010 - 2011</b>
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

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