Observations after 15 years of Platelet Bacterial Screening at the Irish Blood Transfusion Service

Danny Curran
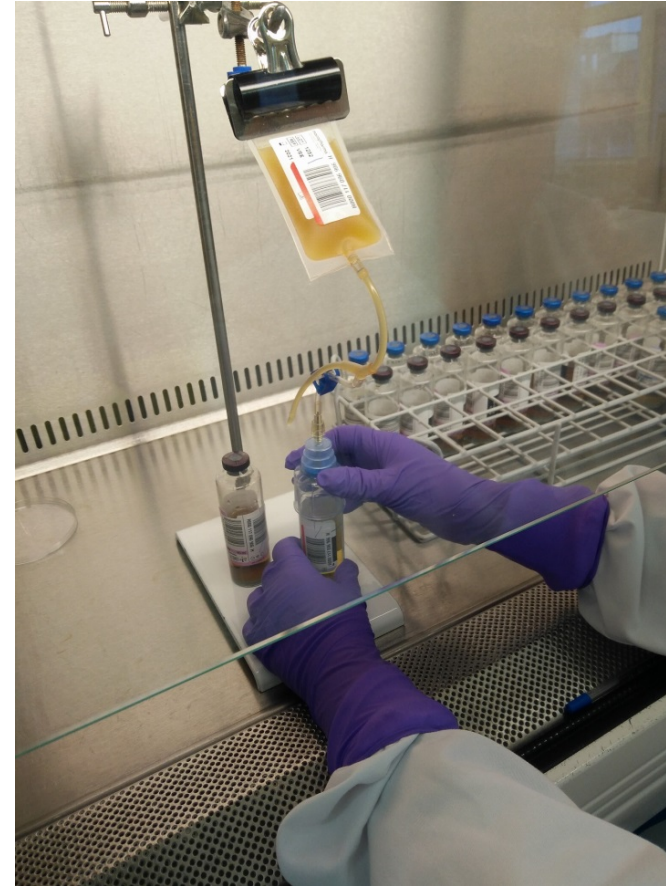
Danny.curran@ibts.ie

3rd October 2018

Timeline

- Nov 2004 Platelet Screening
- Sep 2005 BPN Bottle
- Nov 2005 Day 4 Testing
- July 2007 Orbisac Pools
- March 2015 Testing at the NBC centre only

BacT Testing

Sampling Protocol

- Apheresis sampled day after donation (day 1)
- Pools sampled day after pooling (day 2)
- BPA & BPN bottles
- Incubated to beyond day 5 expiry
  (Aph 4.8 days or 3.8 days Pools)
- Product released after loading verification
- Additional sample day 4 (for 7 day shelf life)
- Loading two batches per day (Mon to Saturday)

Numbers

Overall Program	# Tested	false rate	Non-confirmed rate	confirmed rate
Apheresis	122,311	0.10	0.07	0.04
Pools	76,940	0.37	0.10	0.13

Bacterial Screening Test Results **Apheresis** Platelets
2005-2018 (August)

Apheresis Platelets 2005* - 2018	Donations	Non-confirmed Positives	Non-confirmed Positive Rate %	Confirmed Positives	Confirmed Positive Rate %	Total Positive Rate (confirmed plus non-confirmed) %
Day **1** (Initial) Test	122311	55	0.045	35	0.029	0.073
Day 4 Test	58709**	16	0.027	7	0.012	0.039
Expired (tested on day 8)	2374	1#	0.042	0	0	0.042
Overall	-	**72**	**0.114**	**42**	**0.041**	
					Overall Positive rate	**0.154% (1:649)**

*Post use of BPA & BPN bottles
**Estimated Quantity of donations retested at day 4 (based on a 2016 rate of 48% retested)
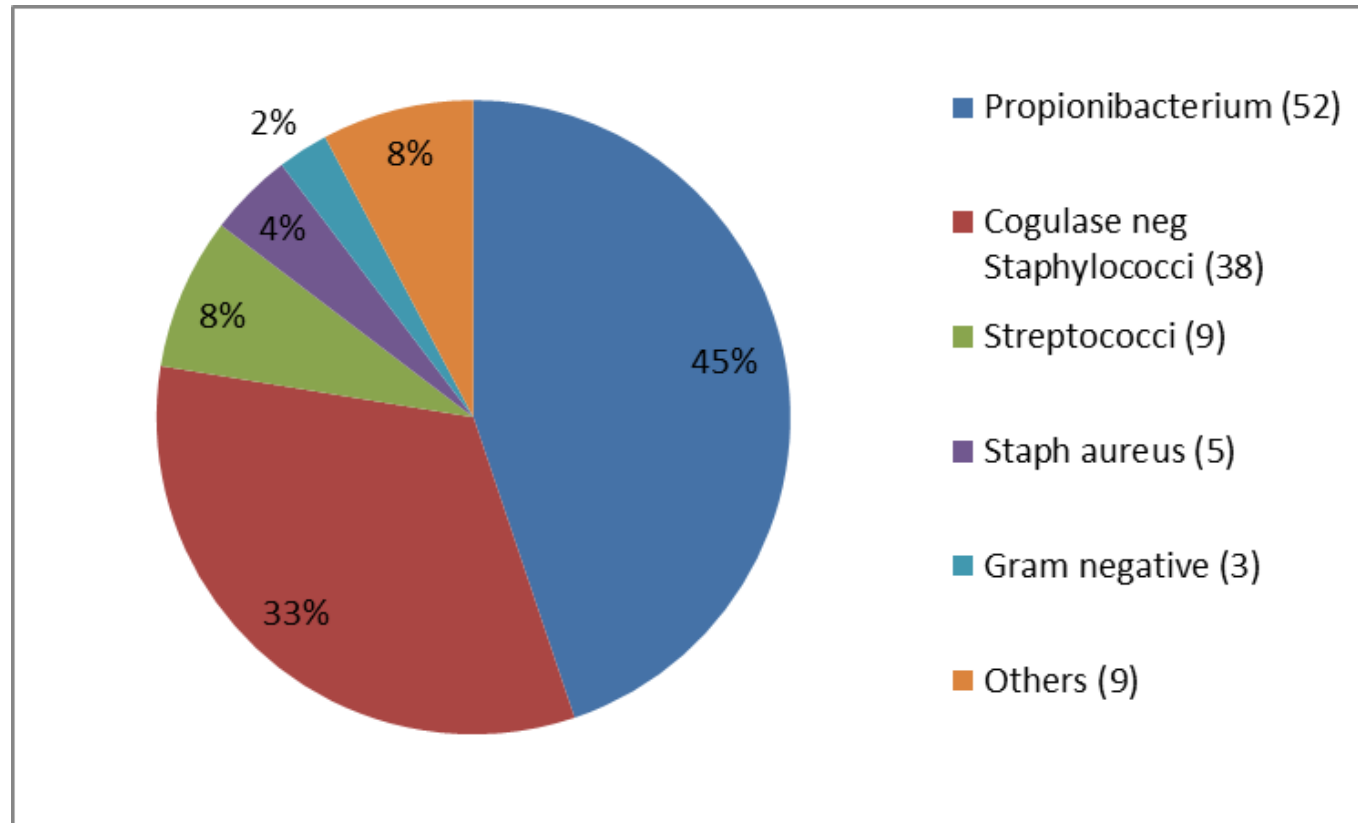 # 2011- re-testing of Product was negative

Bacterial Screening Test Results **Pooled** Platelets 2007-2018 (August)

Pooled Platelets 2007*- 2018	Total	Non-confirmed Positives	Non-confirmed Rate %	Confirmed	Confirmed Rate %	Total Positive Rate (confirmed plus unconfirmed) %
Day 2 (Initial)	76940	42	0.055	65	0.084	**0.139**
Day 4	20615	9	0.044	9	0.044	**0.088**
Expired (tested on day 8)	694	0	0.000	0	0.000	**0.000**
Overall	-	51	**0.099**	74	**0.128**	
					Overall Positive rate	**0.227 %** **(1:441)**

* Post start of Orbisac Pool Platelets
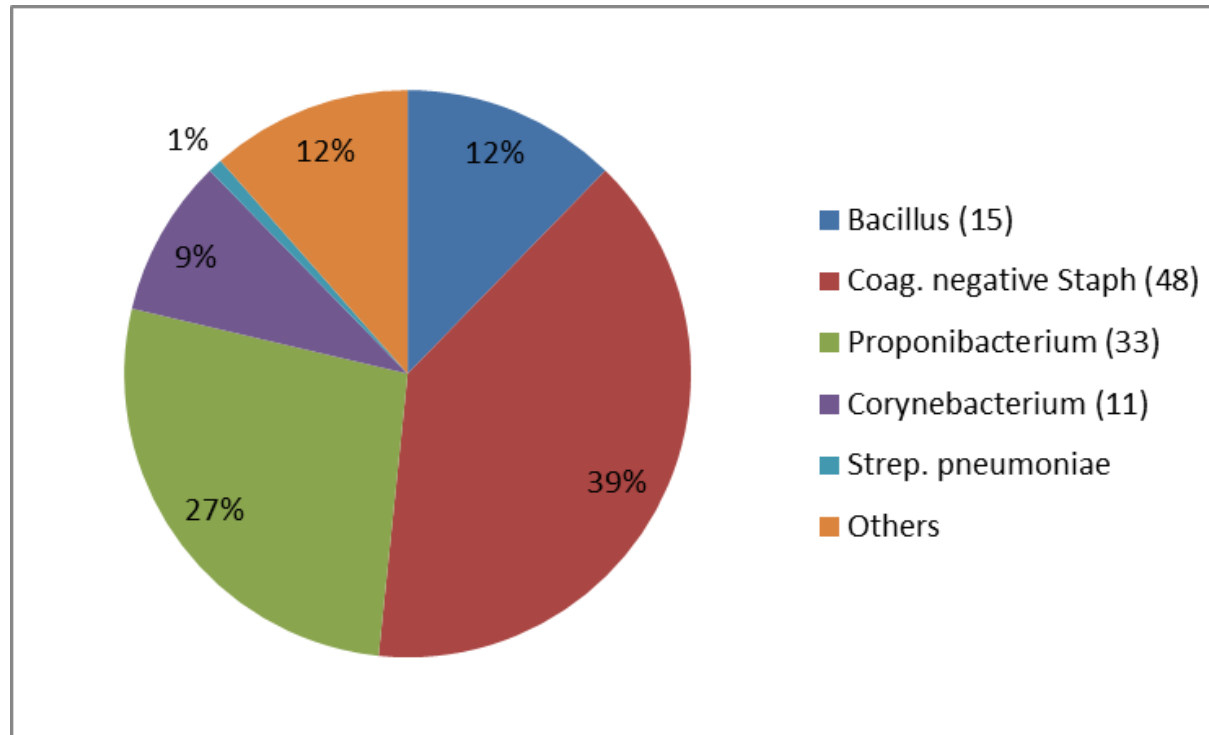
Bacteria isolated

Confirmed positive platelets (116)

Bacteria: Non-confirmed Positives

- 122 Non-confirmed Positives

- 66 had a platelet re-tested

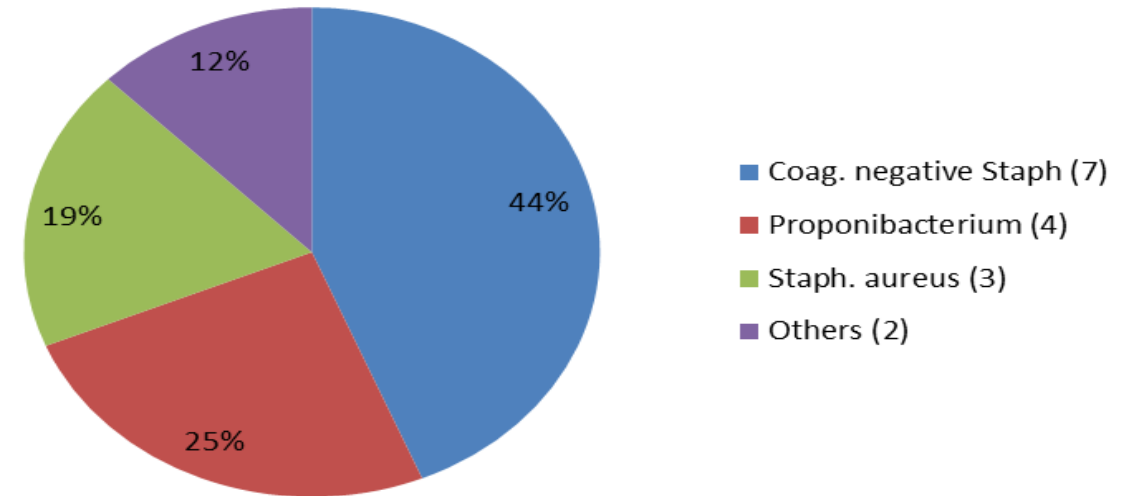- 15 Bacillus (0 Bacillus with confirmed positives).

Day 4 testing Analysis

Initial V day 4 Confirmed Positive rates:

	Initial test Confirmed rate %	Day 4 Test Confirmed rate %	Initial Test Efficacy
Apheresis	0.029	0.012	70.7%
Pools	0.084	0.044	65.6%

Day 4 test Bacteria

	% Propionibacterium spp.	
	Day 2	**Day 4**
Pool Platelets	46.2% (30 out of 65)	33.3% (3 out of 9)
Apheresis Platelets	52.9% (18 out of 34)	14.3% (1 out of 7)

Legend:
- Coag. negative Staph (7) — 44%
- Proponibacterium (4) — 25%
- Staph. aureus (3) — 19%
- Others (2) — 12%

Positive Investigation
Retesting success

- Detection success of positive bacteria in associated Red cells?

Bacteria detected in Pool Platelet	# occurences 4 FRCC Tested	# where FRCC positive	% Recovery in FRCC
Propionibacterium	29	28	96.6%
Staphylococci	27	4	14.8%
Streptococci	7	1	14.3%

- Pool only positive (29 events) – 27 Staphylococci/Streptococci.

- Red cell only positive (7 events) - 5 Propionibacterium.

- <u>**Summary:**</u> Gram positive cocci are very less likely to be detected in Red cell packs.
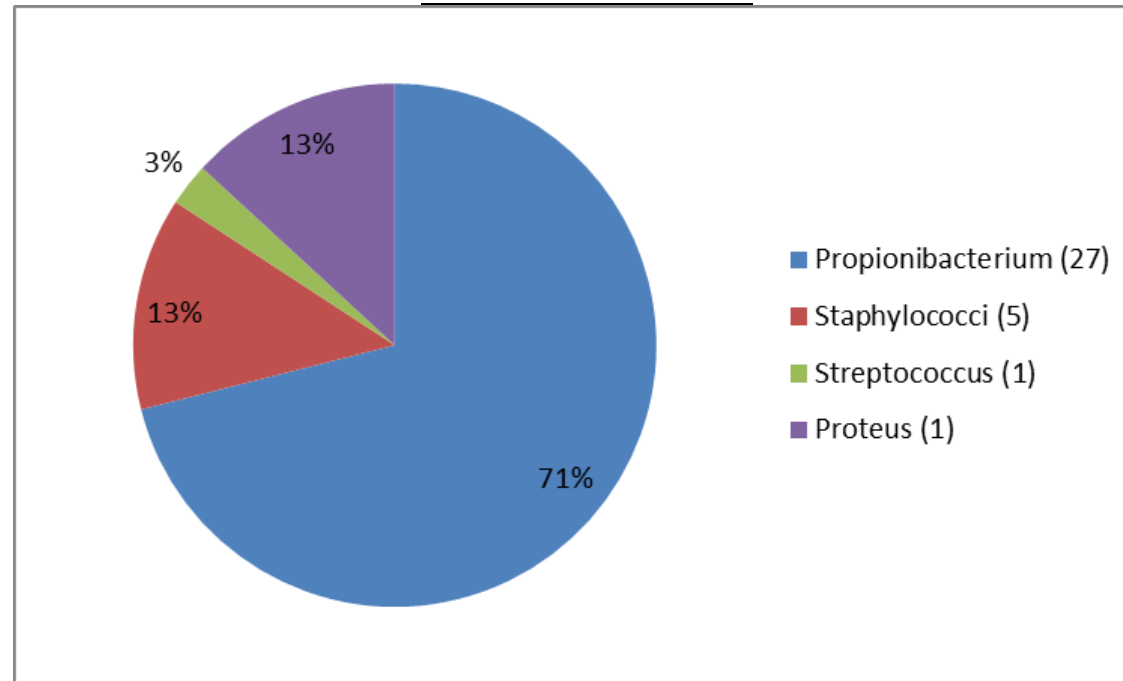
Retesting Product
(Influence of pack Incubation boost)

- 2012 started incubating suspected positive packs at 32°C in tandem with the retest.

- 33% (10 out of 30) initial negative packs then gave a positive result in a further test post incubation.

- E.g. May 2018: Positive pool (initial day 2 sample), P.acnes.

  Day 4 sample negative, Pool initial retest negative & FRCC positive.

  Pool 2nd retest post incubating positive!

- Summary: a portion of non-confirmed results will be confirmed by further testing after incubation of packs.
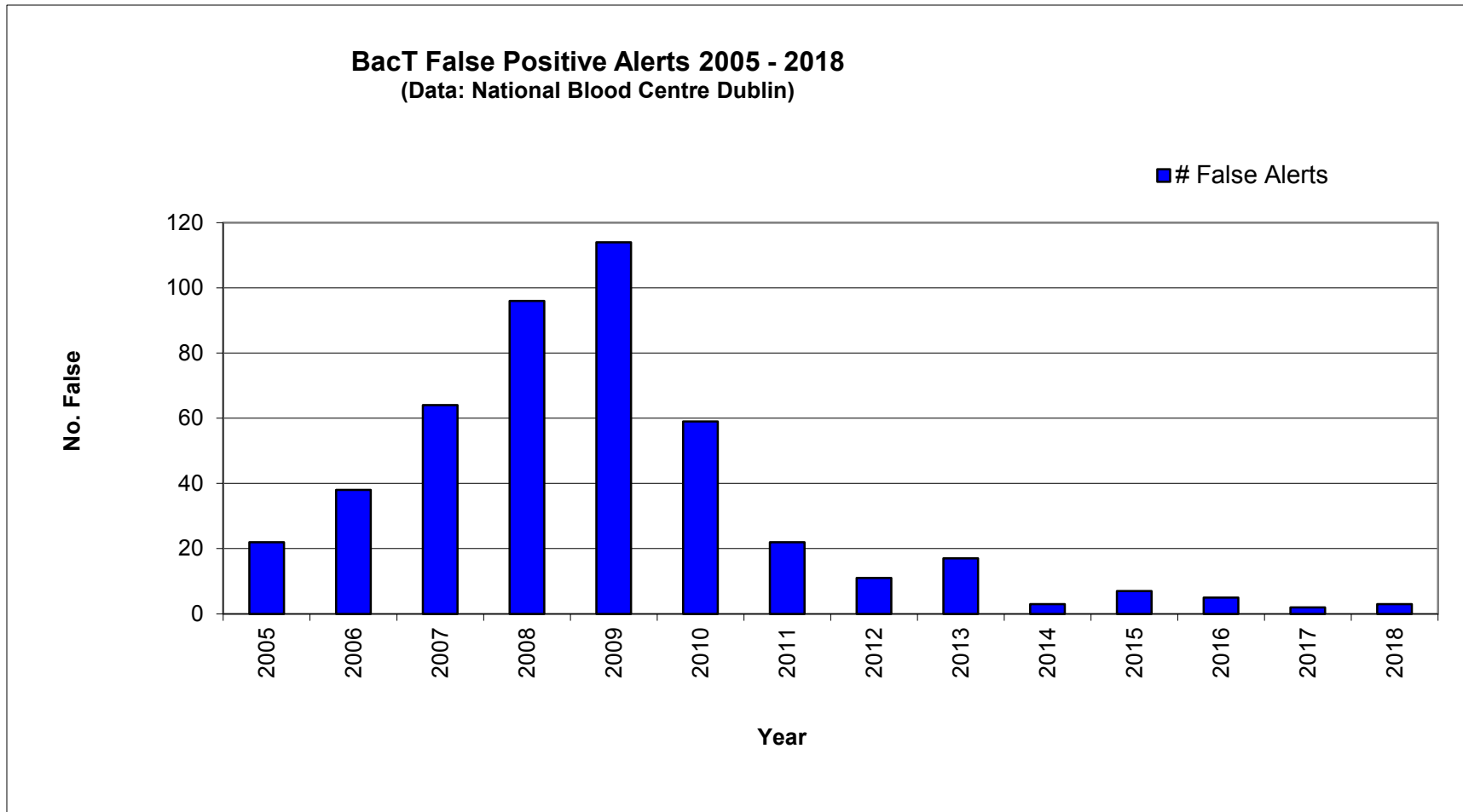
Recall success

- Confirmed positives = 71% Recall success (34/116 platelets infused).

Bacteria infused:

- Total (Conf + Non- Conf) = 63% Recalled (89/238 infused).
- No platelet Septic TTI reported.

False positive history

BacT False Positive Alerts 2005 - 2018
(Data: National Blood Centre Dublin)

PAS influence

	# Products	# Positives	Positive Rate %
Pre-PAS (2004-July 2007)	29,352	12	0.041
Post PAS	76,940	65	0.096

- TTD Apheresis V PAS Pools – no obvious difference noted
- Had a big influence on false positives

Other learnings

- 2011: Controller fault.
- 2015: drawer/rack faults
- 2017 Power interruption..plan contingency
- 2018: Rise in non-confirmed results following disinfectant change - bottle septum disinfection critical

Testing Differences

- Sampling device (pouch/device)
- Sampling method – mother bag/each split
- Sampling time
- One/both bottles
- Incubation time
- Hold time
- Dealing with positives/product recalls
- Testing multiple batches/different centers
- Terminology

= Difficult to directly compare results across different organisations

Future

- Later Apheresis sampling?
- Single test?
- Hold period?
- Link to eprogesa?
- Contingency?
- Pathogen reduction

Thanks to:

- Michael Maher, Senior Medical Scientist
- Dr Niamh O'Flaherty, Consultant Microbiologist