

Routine Screening for Bacterial Contamination

Transfusion Update 08

5th May 2008

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Project Manager - BCS

The Big Questions:

- > Why BCS?
- > Where does contamination come from?
- > What are ARCBS contamination rates?
- > How will the new process work?
- > What happens if a component flags positive?
- > How will BCS affect availability of platelets?
- > What next?

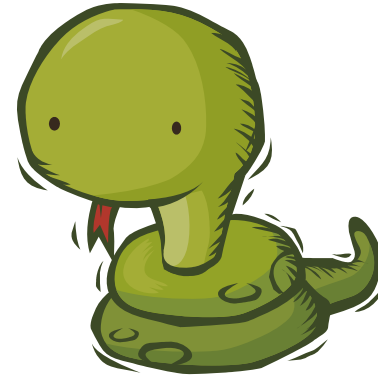
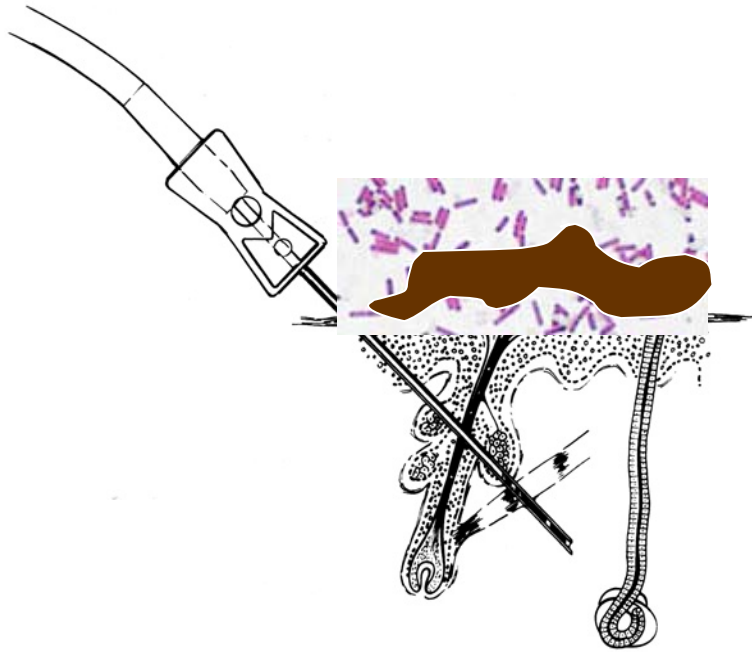
Why BCS?

- > Platelet-transfusion-associated sepsis is the most frequent infectious complication of transfusion therapy
- > Between 1:1000 and 1:3000 platelet units are bacterially contaminated at time of transfusion
- > Estimated to cause life-threatening sepsis in between 10-40% of recipients
- > Worlds best practice is now to screen platelets
- > ARCBS has been progressing resources to implement since 2004

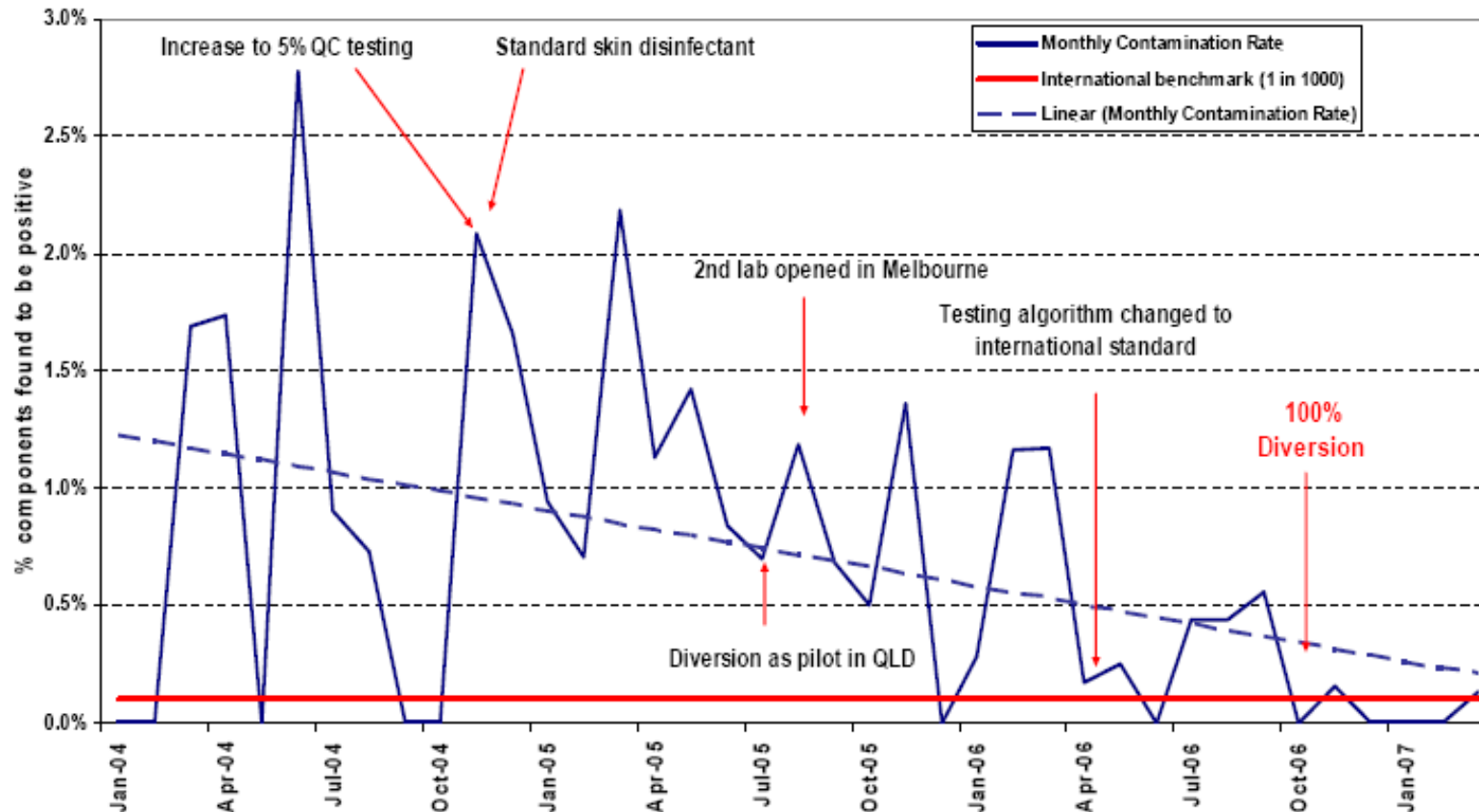
Other infectious risks

Agent	Estimate of residual risk per unit
HIV (antibody and RNA)	< 1 in 10 million
HCV (antibody and RNA)	< 1 in 10 million
HBV (HBsAg)	Approx 1 in 660,000
HTLV I&II antibody	< 1 in 10 million
CMV (antibody negative)	Approx 1 in 27,000
vCJD	Possible. Not yet reported in Australia.
Malaria (antibody)	Approx 1 in 4.9 million – 1 in 10.2 million

Where do the bugs come from?



What are ARCBS contamination rates?



Number of reports to ARCBS of serious, high probability septic transfusions:

- 2005/06: 4.6/100,000 platelets issued, 0.4/100,000 red cells issued
- 2006/07: 2.6/100,000 platelets issued, 0.13/100,000 red cells issued

How will the new process work?

Donor Services
Collection time is identified
Apheresis staff attach donation number to blood component sampling device

Processing
Hold platelet components until >24 hrs post collection
Use NBMS and BCS interface system to determine which units to sample
Create BCS consignment and send samplings to testing laboratory

Bacterial Contamination Screening Laboratory
Inoculate and incubate samples
Result test code in NBMS using the BCS interface program
Inform Processing of sample status

Processing
Release label platelet components

The Process

- > 15mL of component is taken
- > Pooled donations are sampled into an attached sampling pouch



- > Apheresis donations are sampled into a Blood Component Sampling Device



- > Each sample is inoculated into 2 bottles
- > One Aerobic, and one Anaerobic



- > Each bottle contains a nutrient media to facilitate bacterial growth
- > As bacteria grow, CO_2 is produced through respiration
- > $\uparrow \text{CO}_2 \rightarrow \downarrow \text{pH}$
- > A colorimetric indicator on the bottom of each bottle detects the pH change



- > After inoculation, the bottles are loaded on the bioMerieux BacT/ALERT detection system
- > Result of “inoculated” transferred to Progesa
- > Bottles are incubated at 37°C over a period of up to 7 days



What happens if a component flags positive?

- > Initial Machine Positive (IMP) flag by BacT Alert
- > **Components not yet released** from ARCBS:
 - > quarantine and culture platelets and all associated clinical components

Initial Machine Positive 'flag'

- > Initial Machine Positive (IMP) flag by BacT Alert and **platelet issued to laboratory**
- > Contact destination blood bank
- > **If platelet unit not yet transfused:**
 - > follow recall process
 - > lab to quarantine immediately
 - > return to ARCBS for destructive testing
- > Issue replacement component

Initial Machine Positive 'flag'

- > **If platelet unit transfused:**
- > Agreed that each jurisdiction/laboratory will develop their own procedures
 - > Consider patient blood cultures if not already performed and
 - > In high risk patient ?? consider antibiotics
 - > Consider how to manage outpatients
- > ARCBS is preparing an information pack and FAQs document for clinicians

How long will it take to become IMP?

Organism	% of QC detections 06/07	Average Detection Time (hrs)
<i>Propionibacterium sp</i>	44%	78
<i>Bacuillus sp</i>	14%	17:24
<i>Staphylococcus sp</i>	24%	14
Other eg <i>Corynebacterium sp</i> , <i>Citrobacter sp</i> etc	18%	43
Machine false positive (expect about 50% or less to be true positives)		12:24

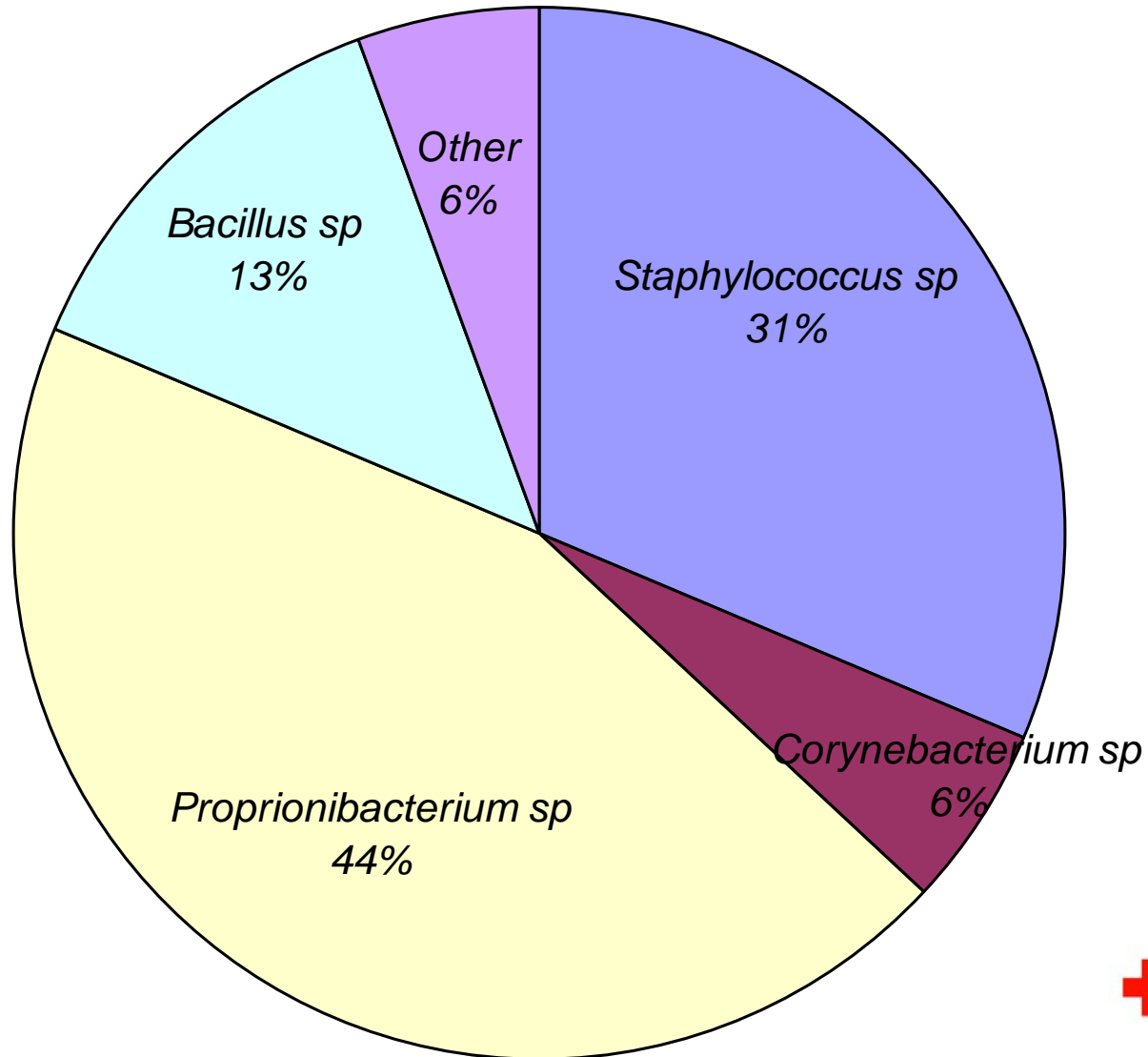
The average time to detection varies with the type of organism and level of contamination. Machine false positives tend to flag earlier, however so do some gram negatives eg *Klebsiella*. All initial machine flags need to be carefully considered.

How long will it take to become IMP?

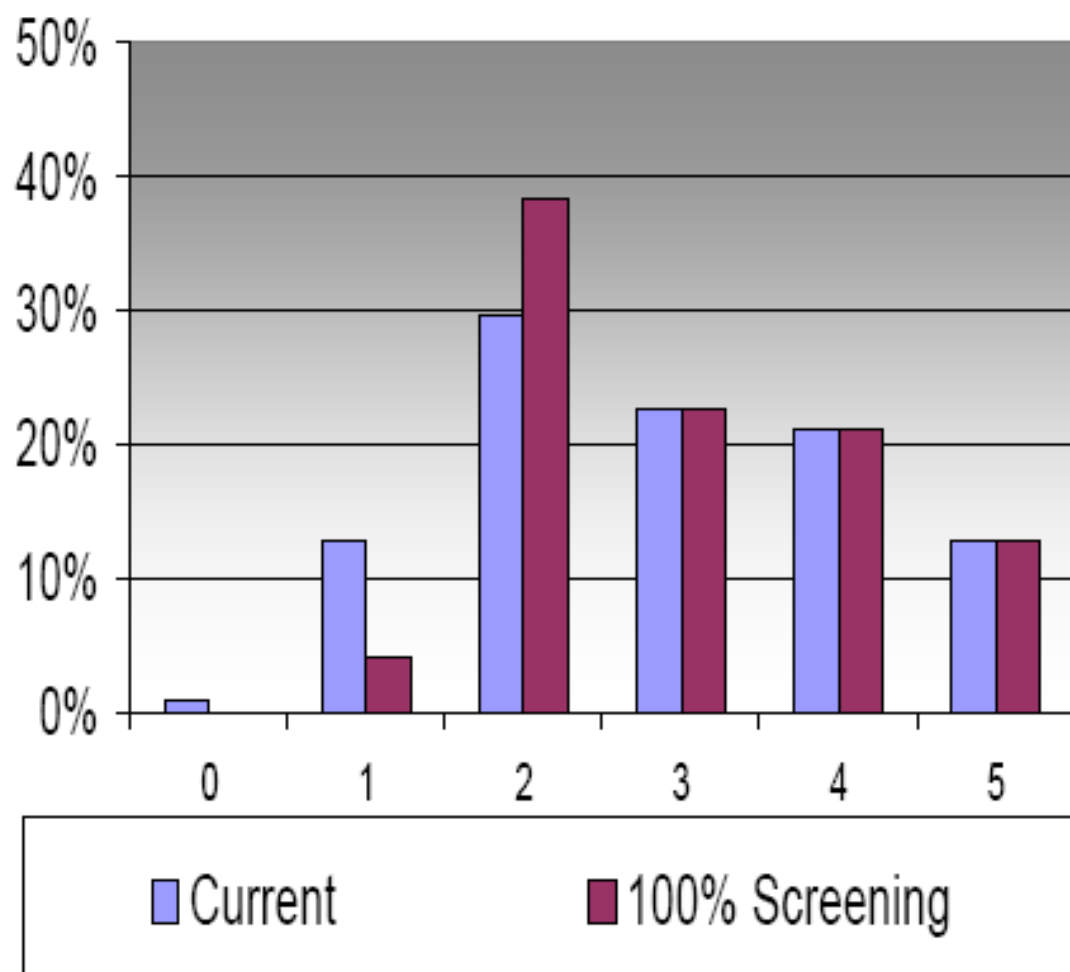
ARC Bacterial Testing on Apheresis Platelets
Time (hours) to Positive
(3/1/04 – 2/29/08)

	<u>Mean</u>	<u>St Dev</u>	<u>Range</u>
True Positive	16.7	8.4	0.0 – 67.2
False Pos (instrument)	18.0	23.1	0.0 – 132.0
False Pos (contamination)	30.2	19.9	2.0 – 120.0
Indeterminate	58.7	35.8	4.1 – 129.6

What sort of Bacteria do we expect?



Expected change in age of platelets at issue



One weeks worth of screening

- > Screening Commenced from collections on 23rd April
- > <Insert DATA>

What next - Phase 2

> Review:

- > How many confirmed positives had still been transfused?
- > How long did it take to detect the bacteria in the initial sample?
- > Could the number of Tx components be reduced by changing the process?
- > Data collection April – October 08
- > Analysis and decisions November – December 08

Questions ?