

# EXPERIENCE ON WHOLE BLOOD BACTERIAL CONTAMINATION

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# BACKGROUND

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- Awareness on bacterial contamination of blood products
- Initial study of Soeterboek et al.: 0.6 % of whole blood units contaminated, but with a large 95 % confidence interval (0.1-2.8 %)
- Possible effect of overnight storage of whole blood on bacterial contamination
- Possible reduction by removal of initial volume, containing the 'skin plug'

# STUDY DESIGN

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## *Phase I*

- Collection of sufficient amount of units to determine accurately the prevalence of bacterial contamination for whole blood collections under standard conditions in the Netherlands

## *Phase II*

- Determination of the effect of diversion of initial flow

# MATERIALS AND METHODS

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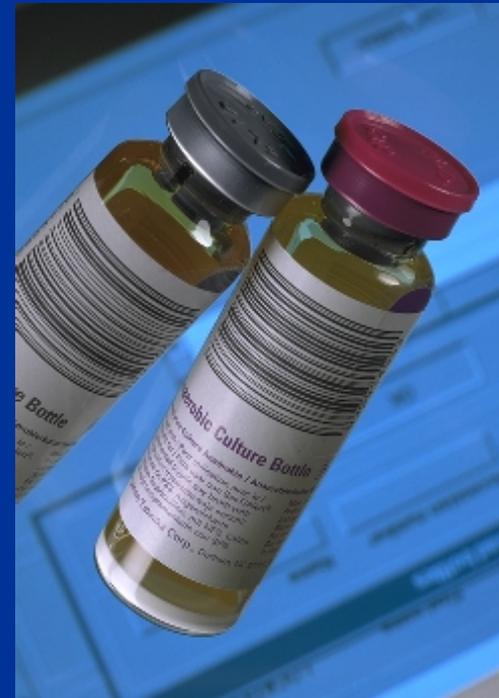


- BacT/Alert® system (Organon Teknika), CO<sub>2</sub> production measured

# BacT/Alert® system



incubator



Culture bottles

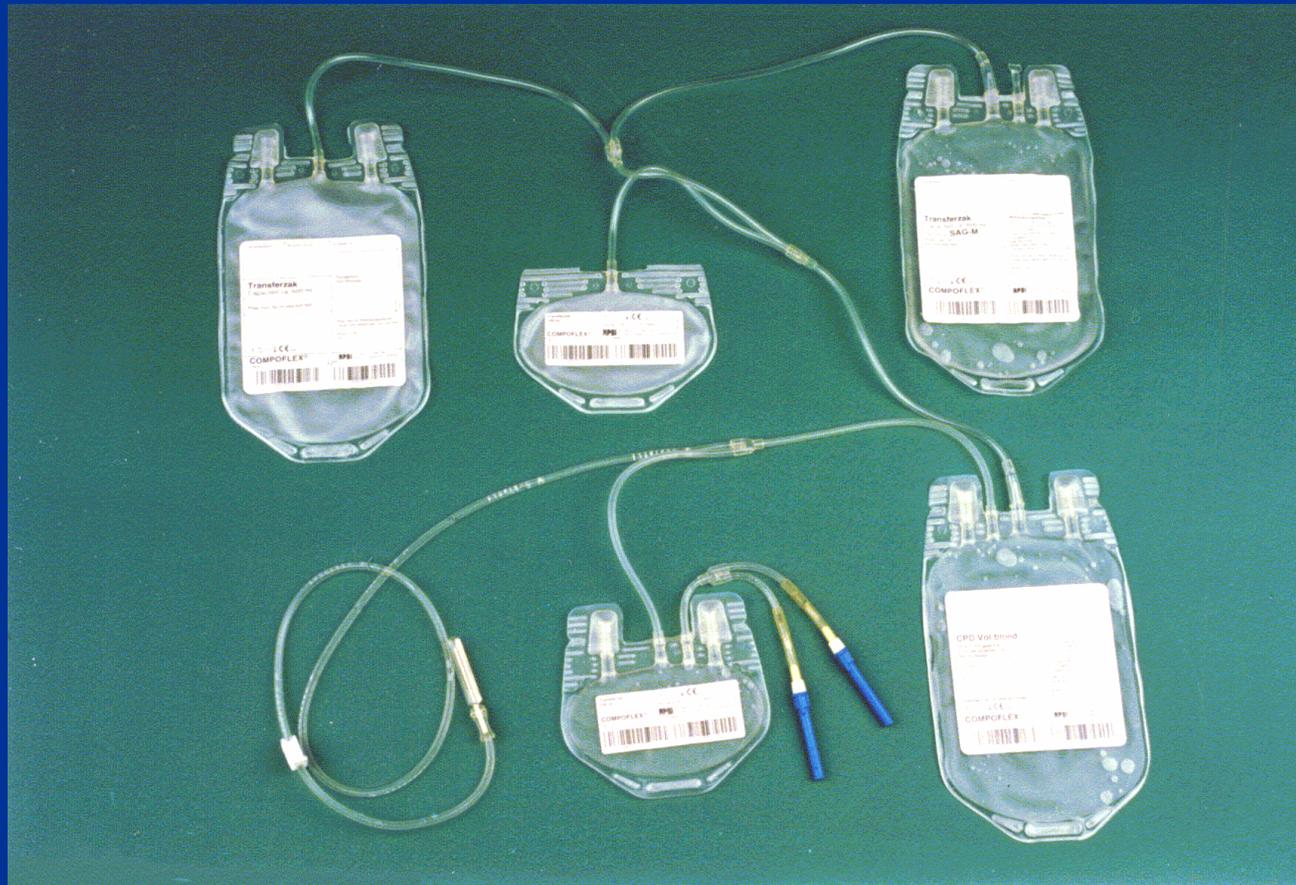
# MATERIALS AND METHODS (ctd)

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- BacT/Alert® system (Organon Teknika), CO<sub>2</sub> production measured
- Modified Compoflex® 4-bag system (Fresenius/NPBI) with additional sampling bag and needles

# Special 5-bag system



# VALIDATION OF SPECIAL 5-BAG

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- Collections, equal to standard bag system
- F VIII content in plasma: no difference
- component preparation: normal
- storage of erythrocytes: normal
- storage of platelets: normal
  
- sample in sampling bag:  
representative for whole unit

# MATERIALS AND METHODS (ctd)

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- 7 days culture, 35°C. Positive signal: culture on blood agar plate, anaerobic and aerobic
- Standardized disinfection (FDA-approved) and collection methods
- Sole aseptic handling is transfer to BacT/Alert culture bottle (anaerobic and aerobic) in a laminar flow cabinet

# AIMS OF PHASE I

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- Reliable determination of prevalence of bacterial contamination of whole blood units (with 95 % confidence interval  $< 0.5$  %)
- Testing the effect of overnight storage as whole blood:
  - Group I: sampling/culture within 3 h
  - Group II: sampling/culture after overnight/20°C

# RESULTS PHASE I



- Group I (within 2 hours): 9219 units collected; 27 units positive (i.e. **0.29 %**; 95 % confidence interval 0.19 - 0.43)
- Group II (overnight 20°C): 9038 units collected; 36 units positive (i.e. **0.39 %**; 95 % confidence interval 0.28 - 0.55)
- **No significant difference**, overall prevalence of whole blood contamination with bacteria: 0.34 %

## DIFFERENTIATION OF POSITIVE SAMPLES

	group I	group II
<i>Staphylococcus sp. CNS</i>	8	17
<i>Propionibacterium sp.</i>	10	17
<i>Diphtheroids, Corynebacterium sp.</i>	5	0
<i>Bacillus sp</i>	2	1
<i>Micrococcus sp.</i>	1	0
<i>Peptostreptococcus sp.</i>	1	0
not identified	0	1

## RESULTS PHASE I (ctd)

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- Similar distribution of species in both groups
- Mainly skin-associated, not 'pathogenic'
- *Peptostreptococcus* case: probably not intrinsic, also transient skin flora.

# CONCLUSIONS PHASE I

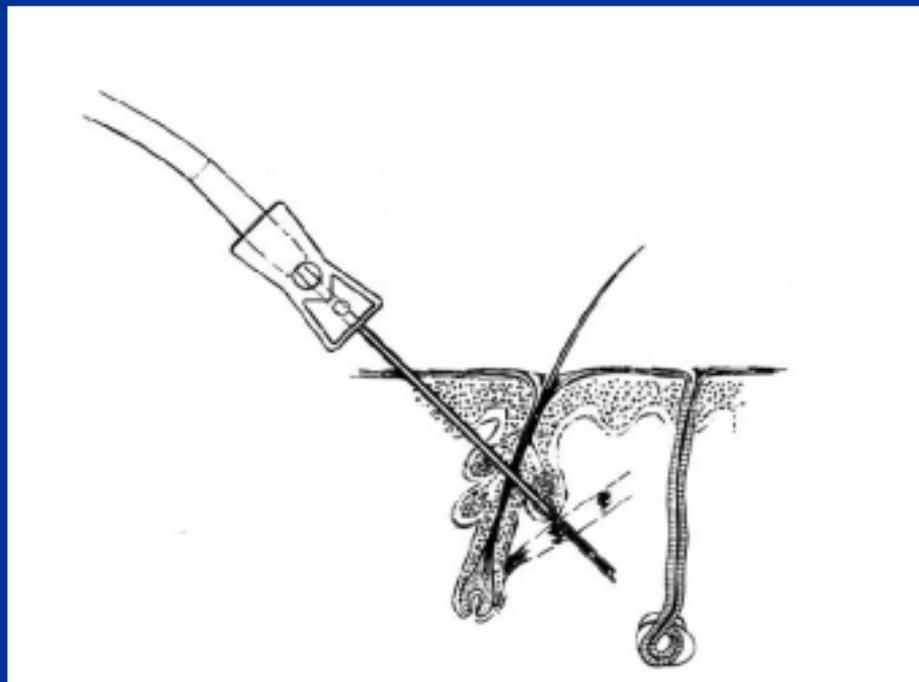


- Prevalence of bacterial contamination in whole blood collections is **0.34 %** (lower than previously reported) with a small 95 % confidence interval
- Mainly skin-derived bacterial contamination: part should be preventable by improved disinfection and/or removal of first amount of blood
- No direct effect of overnight storage as whole blood (leukocytes have to be removed for the reported effect)

## BACKGROUND PHASE II



- Possible reduction by removal of initial collected volume containing the 'skin plug'



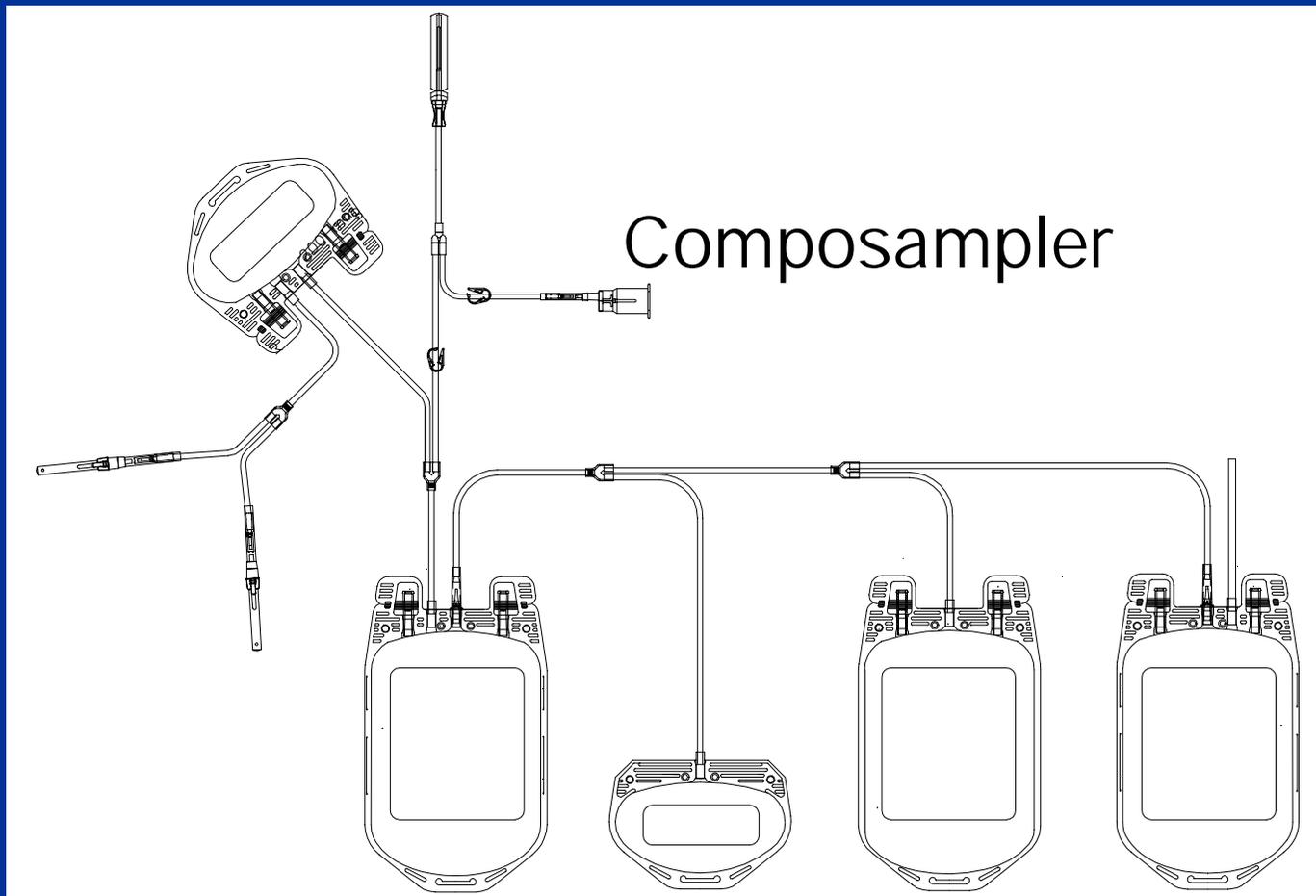
# MATERIALS AND METHODS Phase II

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- Modified Compoflex<sup>®</sup> 4-bag system (Fresenius/NPBI) with Composampler<sup>®</sup> and additional sampling bag and needles
- other materials & methods same as Phase I
  
- Modified bag system was validated, like the system used in Phase I

# Special 5-bag system with Composampler®



## AIMS OF PHASE II

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- Measurement of the prevalence of bacterial contamination in whole blood units after diversion of the first 10 ml (with the determined prevalence in phase I as base level)
- Testing the effect of diversion in two groups:  
Group I: sampling/culture within 3 h  
Group II: sampling/culture after overnight/20°C

## RESULTS OF PHASE II



	Standard whole blood collection	Diversion of the 1 <sup>st</sup> 10 ml
Donations tested	18,257	7,115
Prevalence	0.34%	0.21%
Confidence interval	0.25-0.44	0.12-0.35

## RESULTS PHASE II (ctd)

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- After removal of the first 10-ml, the prevalence of bacteria was for both groups 0.21 %
- Group with immediate sampling: not significant
- Group with overnight sampling: significant decrease
- Total study: significant decrease:  $p < 0.05$

## DIFFERENTIATION OF POSITIVE SAMPLES

	Phase I	Phase II
<i>Staphylococcus sp.</i> CNS	25	2
<i>Propionibacterium sp.</i>	27	10
<i>Diphtheroids, Corynebacterium sp.</i>	5	0
<i>Bacillus sp</i>	3	0
<i>Micrococcus sp.</i>	1	0
<i>Peptostreptococcus sp.</i>	1	0
<i>Streptococcus bovis</i>	0	1
<i>Gemella morbillorum</i>	0	1
<i>Klebsiella pneumonia</i>	0	1
not identified	1	0

## RESULTS PHASE II (ctd)

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- The majority of bacteria were identified as *Propionibacterium species* (skin flora).
- A significant decrease of the prevalence of *Staphylococcus species* ( $p = 0.015$ ) was found.

# DISCUSSION

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- findings supported by:  
Wagner: study with *in vitro* model  
Bruneau: indirect evidence by measuring the contamination in the first two fractions during collection
- why only *Staphylococcus sp.* decreased?  
no real skin plugs but flaps?

## DISCUSSION (ctd)



- Even after introduction of this preventive measure, the theoretical contamination risk of random donor pooled platelet concentrates composed out of 5 single donor units is still considerable: about 1%. Additional testing required.
- First volume can be used for test purposes, provided that collection system can be assigned as "closed".

# CONCLUSIONS

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- Prevalence of bacterial contamination in whole blood collections is **0.34** % with a small 95 % confidence interval
- Prevalence of bacterial contamination in whole blood collections can be reduced significantly by removal of first amount of blood
- No gram negative bacteria cultured out of a total of 18,000 units of whole blood

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