Diversion of Initial Volume of Collected Blood to a Separate Container;

consideration of benefits and design of collection system

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Bacterial Contamination Rate for Blood Products-

Blajchman, M., FDA Workshop on Bacterial contamination of platelets, 1999

• Random donor platelets	1/3000 units
• Pooled random donor units (4-6)	1/500 units
• Apheresis platelets	1/5000 units
• Red Blood cells	1/30,000 units

• Viral contamination (HCV, HBV, HIV)	1/100,000+

Bacteria identified in contaminated blood products

- *Staphylococcus epidermidis*
- *Staphylococcus aureus*
- *Bacillus cereus*
- *Echerichia coli*
- *Klebsiella pneumoniae*
- *Serratia marcescens*
- *Clostridium perfringerns*
- *Streptococcus pyogenes*
- *Propionibacterium acnes*
- *Corynebacterium diphtheroides*
- *Aspergillus terrus*
- *Streptococcus viridans*
- *Salmonella typhimirium*
- *Yersinia enterocolitica*
- *Pseudomonas fluorescens*
- *Pseudomonas aeruginosa*
- *Enterobacter aerogenes*
- *Enterobacter cloacae*
- *Serratia liquefaciens*
- *Pseudomonas putida*
- *Salmonella choleriasuis*

Factors Affecting Patient Outcome With Transfusion of Bacterially Contaminated Blood Products-

Krishnan & Brecher, Hematology/Oncology Clinics of North America, 9:167-185, 1995

- V Virulence of the organism
- I Immune status and general condition of the recipient
- C Concentration and bolus dose of bacteria transfused
- T Timely recognition and and therapeutic intervention
- I Intensity of patient monitoring, i.e., inpatient vs outpatient
- M Medicine the patient is receiving, i.e., antibiotics

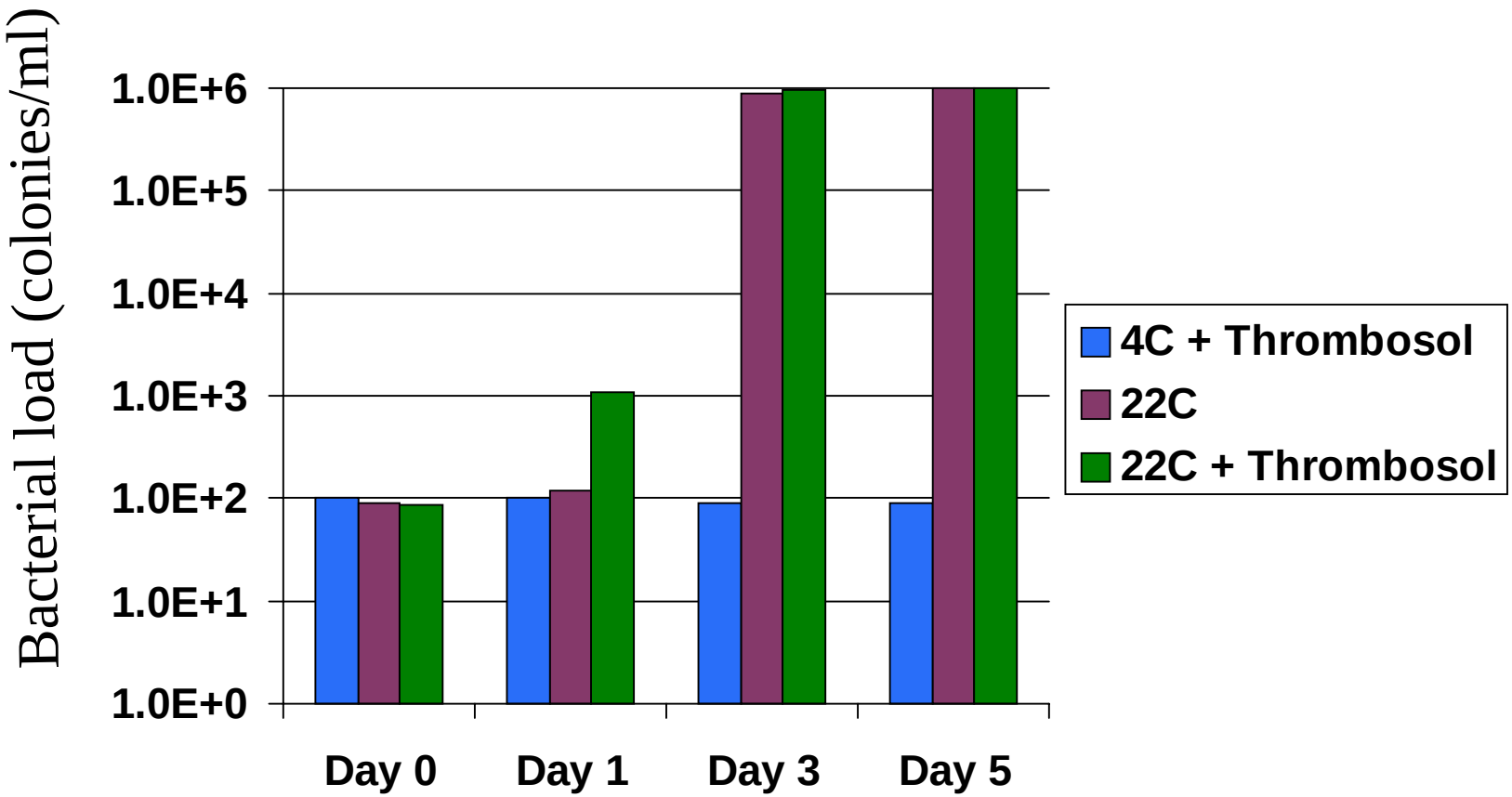
Bacteria Associated With Transfusion Fatalities Reported to the FDA 1976-1998

Red Blood Cells (%)	**Platelets (%)**	**RBC and Platelets (%)**
Y. enterocolitica (17)	*S. epidermidis (6)*	*Klebsiella spp. (12)*
C. perfringens (1)	*E. coli (4)*	*S. aureus (12)*
P. acnes (1)	*Bacillus spp. (4)*	*Serratia (12)*
Enterococcus (1)	*Streptococcus (5)*	*Pseudomonas (7)*
	Salmonella spp. (5)	*Enterobacter spp. (6)*
	P. mirabilis (1)	

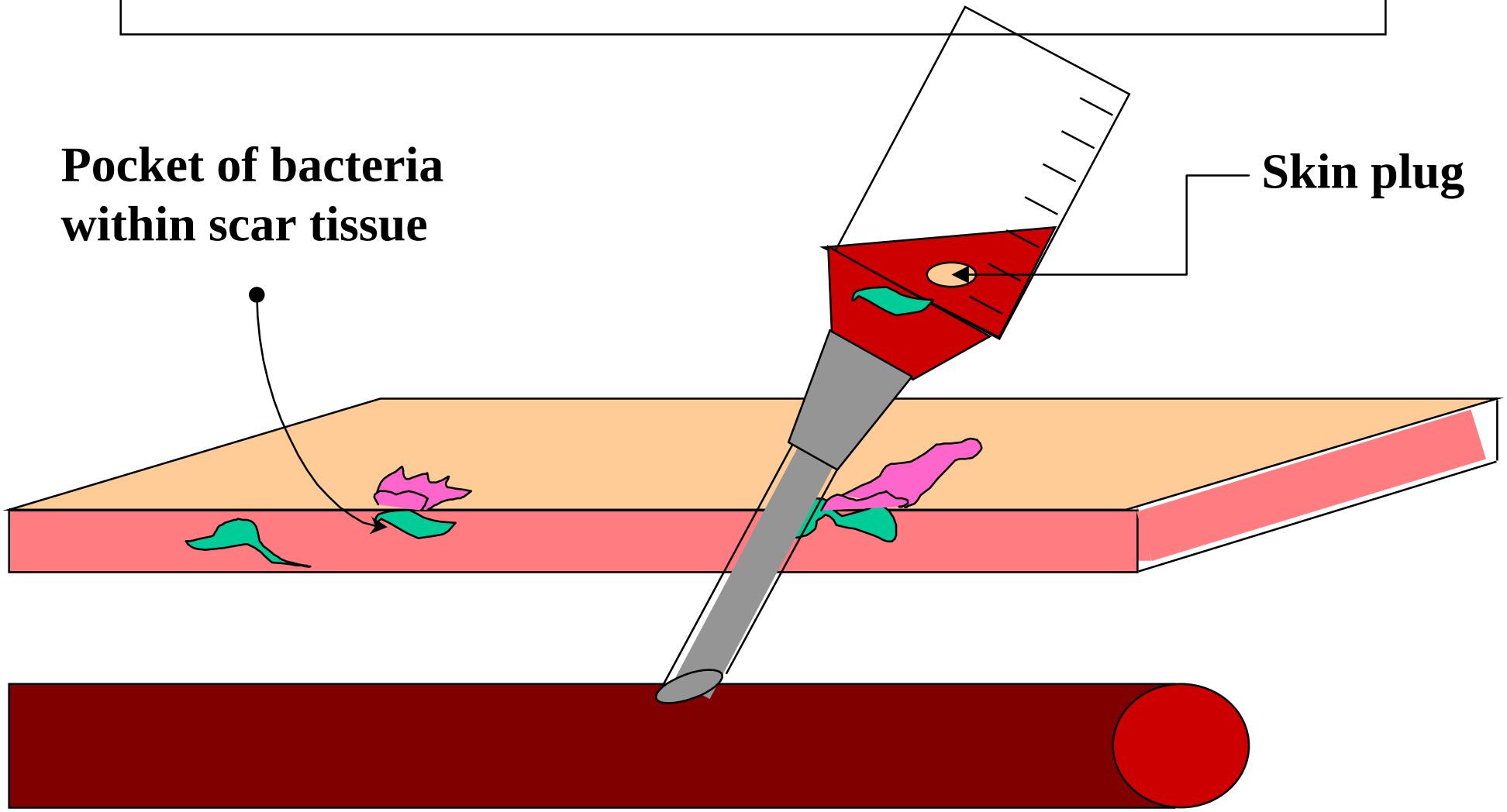
Organisms identified in 78 cases from a total of 84 transfusion transmitted sepsis-associated fatalities reported to the FDA between 1976 and 1998 (Lee, J-H, FDA workshop on Bacterial Contamination of Platelets, 1999)

Growth of *S. aureus* in intentionally inoculated PCs

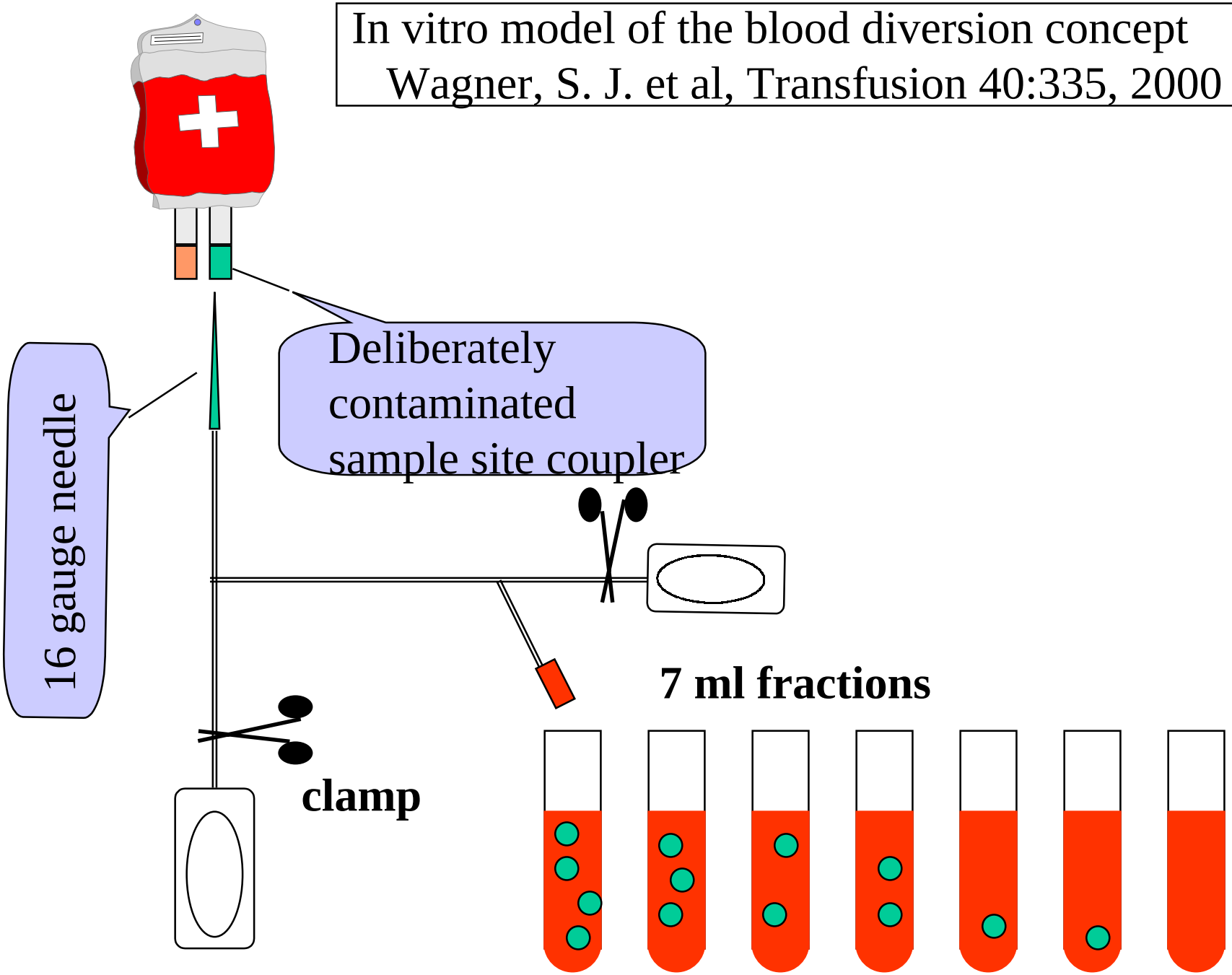
data from: Currie et al. TRANSFUSION 37:18-24, 1997



Bacterial Contamination of Collected Blood by Needle Cutting Through Skin



In vitro model of the blood diversion concept
Wagner, S. J. et al, Transfusion 40:335, 2000



CFU counts in sequential blood tubes sampled through a intentionally contaminated sample site coupler-
Wagner, S., Transfusion, 40:335, 2000

tube

Exp	Initial CFU	**1**	**2**	**3**	**4**	**5**	**6**	40 ml pack	Two-port bag
1	0	164,500	21,840	24,920	19,320	10,080	2,912	19,000	2,000
2	0	476,000	31,360	21,560	15,260	8,750	4,082	9,560	2,000
3	0	207,200	12,880	11,830	6,090	2,520	2,310	13,200	3,300

88.5% | 95.3%

cumulative percentage of S. aureus "capture"

Diversion of initial blood to a separate bag

- DESIGN
- closed system
- diverted blood is separated from final blood product by unidirectional flow
- volume of diverted blood is sufficient to achieve potential benefits

- POTENTIAL BENEFITS
- decrease product loss due to inadequate sample collection
- decrease bacterial contamination of product