2% Chlorhexidine Gluconate in 70% Isopropyl Alcohol Donor Arm Scrub Validation

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Background: In 1994 a large multi center blood collection facility compared the two-step Blood Donor Prep Kit (70% alcohol Sepp® and a 2% iodine tincture Frepp®) to 10% povidone-iodine. Positive skin cultures were lowest using the Blood Donor Prep Kit. As a result of this validation the blood center switched donor arm prep agents.
In 2003 the US Food and Drug Administration (FDA) issued "Options for Arm Preparation", which detailed FDA approved arm preparation procedures. The blood center conducted a Donor Arm Prep validation in 3 facilities comparing two of the four approved arm prep procedures. The objective was to determine the efficiency of 2% chlorhexidine in 70% isopropyl alcohol (ChloraPrep® 1.5 mL Frepp® Applicator) to their current two-step Blood Donor Prep Kit.

Study Design: The validation was divided into two parts. First, a site was selected to do a focused validation that required one specifically trained individual to do side-by-side scrubs and collect skin cultures for colony counts on 40 different volunteers/potential donors. The second part of the validation occurred in two additional sites where several different individuals were trained to do side-by-side scrubs and collect skin cultures for colony counts on 100 different volunteers/potential donors per site.

RESULTS:

Arm Preparation Agent	Site 1 n=40	Site 2* n=100	Site 3 n=100
CHG/IPA	36 no growth 4 growth ≤ 10 CFU	86 no growth 3 growth ≤ 10 CFU 11 growth > 10 CFU	99 no growth 1 growth ≤ 10 CFU
Blood Donor Prep Kit	31 no growth 9 growth ≤ 10 CFU	88 no growth 4 growth ≤ 10 CFU 8 growth > 10 CFU	98 no growth 2 growth ≤ 10 CFU

*Discrepancies in sampling errors and collection area contamination

Conclusion: The 2% chlorhexidine in 70% isopropyl (CHG/IPA) alcohol solution demonstrated efficacy comparable to the Blood Donor Prep Kit. The CHG/IPA prep offers the following advantages; 1) a one-step prep procedure, therefore reducing donor arm preparation time and 2) an alternative prep for donors allergic to iodine.