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Quality Management of the Blood Component Production Process Using Boeing Statistical Process Control Methods Adapted Excel-based Applications

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Introduction: Records from 2005 indicated a great variability in the use of performance indicators at different blood component production process control points.

Failure mode analysis of the production process showed that human and material resources are the main risk factors for nonconformity of blood components, and that adequate, in-time, corrective and preventive measures are the key success factors for process quality management.

Methods: A statistical process control (SPC) system was built based on the Boeing methods, considering each blood donation as a different production lot, and using the conditional color-formatting functions of Excel tables. These allowed for an immediate visual signal, which points to the corrective measure to be taken. Systematically followed parameters, such as measurements validity indicators, initial, intermediate and final process control points performance indicators, and process efficiency indicators recorded since 2000 were used to validate the SPC system.

Results: After six months of use, a statistically significant reduction in variability of different quality parameters such as component weights, cell counts, and active substances contents was identified.

Conclusions: Such a SPC system indicates that 100%, and certainly not 1%, blood component conformity control should be mandatory. Random human mistakes and material dysfunctions are the most frequently encountered process failure modes.

Keywords: blood component production; human error; performance indicators; statistical process control

Transfusion—Transmissible Viral Infections Among US Military Emergency Transfusion Recipients

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Introduction: US military doctrine permits the use of non-Food and Drug Administration-regulated freshly collected blood products to save the lives of patients. The risks of transfusion-transmitted infections (TTI) related to battlefield transfusion of unscreened blood products are not well characterized.

Methods: US service members who received emergency transfusion products in Iraq and Afghanistan (01 March 2002–30 September 2007), were evaluated for hepatitis C (HCV), hepatitis B (HBV), and HIV-1 infections using reposed pre- and post-transfusion sera. Selected regions of viral genomes from epidemiologically linked infected donors and their recipients were sequenced and compared.

Results: Of 761 US emergency transfusion recipients, 475 had sera available for testing: 475 were tested for HCV, 472 for HIV-1, and 469 for HBV. One transfusion-transmitted HCV infection (incidence rate: 2.1 per 1,000 person-years, 95% CI = 0.1–11.7) was identified. The number of pre-transfusion infections was: HCV-4 (0.8%, 95% CI = 0.2–2.1%); HBV-11 (2.4%, 95% CI = 1.2–4.3%); HIV-1-0 (0.0%, 95% CI = 0.0–0.8%).

Conclusions: One TTI (HCV) was associated with the use of emergency blood products. The pre-transfusion HCV and HBV prevalence in transfusion recipients, for an eligible donor population, indicate further studies are warranted to characterize the actual deployed force donor population and these donors’ TTI prevalence. These data will inform countermeasure development and clinical decision-making.

Keywords: blood donors; transfusion-transmissible; viral infections