No Transmission of Viral Hepatitis in Man following Application of Cold-Sterilized Prothrombin Complex Concentrates

D.		Heinrich
R.		Kotischke

D. Heinrich, Beethovenstrasse 46, D-6301 Leihgestern (FRG)

The incidence of viral hepatitis following transfusion of prothrombin complex concentrates (PCC) has been reported to be between 24 and 67%. Screening of donors and blood products for serological hepatitis has not eliminated this risk. Therefore, efforts should be directed towards removal or inactivation of hepatitis virus contaminating PCC and other 'high-risk' plasma products. Treatment of plasma pools with β -propiolactone and UV irradiation, a method inaugurated by LoGrippo, has been proven to effectively inactivate a number of viruses. PCC sterilized by this procedure have been applied to juvenile chimpanzees by Prince without transmission of viral hepatitis. To further evaluate the safety of these cold-sterilized PCC in man, 5 males decided to volunteer for a prospective study in order to help establish the safety of this product. Before and up to 30 weeks after application of 500 U of cold-sterilized PCC to these 5 male volunteers the following hepatitis parameters were determined: SGOT, SGPT, γ -GT, alkaline phosphatase, total bilirubin, HBsAg, Anti-HBs and Anti-HBc. The results obtained prove that there was no indication for transmission of viral hepatitis up to 30 weeks after PCC application.