

ONE YEAR EXPERIENCE AFTER IMPLEMENTATION OF ANTI-HBC TESTING INTO BLOOD DONOR SCREENING IN GERMANY (P-225)

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BACKGROUND AND OBJECTIVES

Introduction of NAT into blood screening reduced the residual risk for transfusion transmitted HCV and HIV infections to a closed to zero risk. In contrast the risk for HBV is at least one log phase higher. Especially chronic HBV carriers may escape routine blood screening because of viral load below the mini-pool NAT detection limit and undetectable HBsAg. To close the diagnostic gap anti-HBc was introduced into blood donors screening in February 2006 and is mandatory in Germany since October 2006.

STUDY DESIGN AND METHODS

To comply with legal requirements Anti-HBc repeat reactive samples were additionally tested for anti-HBs and HBV ID-NAT (sensitivity <12 IU/mL). Products of all anti-HBc repeat reactive first-time donors were discarded. Cellular components of anti-HBc repeat reactive multiple-time donors are discarded if Anti-HBs titer is <100 IU/l. Plasma of anti-HBc positive, ID-NAT negative and anti-HBs positive donors is used as source plasma. Look-back investigations are indicated for ID-NAT positive multiple-time donors or donors with apparent seroconversion.

RESULTS

More than 1 million donations from 5 different geographic areas were screened for Anti-HBc. Prevalence of anti-HBc in first time donors demonstrated regional differences between eastern and western parts of Germany as well as between urban and rural regions. Because Anti-HBc repeat reactive multiple time donors with anti-HBs titers <100 IU/l were rejected from donation the prevalence in our blood donor population was reduced from 1.8% to 0.3% in high prevalence regions.

The incidence was extremely low at 0.003%. In total 14 donors (8 multiple time donors and 6 first time donors) were HBV DNA positive with virus load in a range between 1 to 30 IU/mL. Look back examination did not confirm a HBV transmission. Cost calculation for Anti-HBc-testing per QALY gained if every infectious blood product would cause an infection yielded 687,869€.

CONCLUSION

Implementation of Anti-HBc into blood donor screening causes a loss of 1.8% of blood donors in high prevalence regions. Although more than 27,000 donations were screened by ID-NAT and 14 HBV DNA positive donors were identified no transfusion transmitted infection was identified. Therefore the cost per QALY gained is high but comparable to other NAT screening methods (e. g. HIV-1 NAT or HCV NAT). Unless pathogen inactivation methods for all blood products especially for red cells are available the decision-makers in the health care system have to define the maximal acceptable cost-benefit relation as well as the level and goal of their blood product safety procedures.