

Testing blood donations for hepatitis E virus

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Executive summary

Health Council of the Netherlands



Background and request for advice

Since July 2017, Sanquin Blood Supply Foundation has been testing all blood donations for infection with hepatitis E virus (HEV), as HEV can cause serious health problems in patients with a weakened immune system. The then State Secretary for Health, Welfare and Sport requested advice from the Health Council of the Netherlands with regard to HEV screening. He asked whether testing blood donations is the most (cost) effective method for protecting high-risk patients against HEV infection, whether testing only a portion of all labile blood products would be safe and efficient, and whether there are other measures for protecting high-risk patients against infection. The Committee on Blood Donations and Hepatitis E Virus was established to answer these questions.

Hepatitis E virus

The Netherlands is among the European countries with the highest number of HEV infections. The number of new infections per

year is estimated at 133,000. Infected pigs are the most important source of infection, and transmission mainly takes place via infected food products. HEV can also be transmitted via blood products (blood transfusion). An infected blood product does not always cause infection in the recipient. The probability of infection depends, among other factors, on the amount of virus particles in the blood product.

Consequences of HEV infection

HEV infection seldom leads to illness in healthy persons. Persons with a normally functioning immune system can develop an acute inflammation of the liver, but this usually heals spontaneously within a few weeks. However, if the person in question has a pre-existing liver condition, an acute inflammation of the liver can have serious and even fatal consequences. Persons with a weakened immune system, for example transplant patients and persons with leukaemia, can develop a chronic infection. This can cause serious and irrecoverable damage to

the liver. A chronic HEV infection can sometimes be treated successfully by suspending the use of medication that suppresses the immune system. Treatment can also take place by administering antiviral medication (ribavirin). This is successful in the majority of cases, but not always.

Measures for the prevention of HEV infection

A structural approach against HEV infection requires measures in the food chain. Although dietary guidelines have been developed for high-risk patients, infected food is the main source of infection even among these patients. Effective measures in the food chain would also limit the number of infections among blood donors, in which case fewer blood donations would be infectious. As long as there are no (demonstrably) effective measures in the food chain, testing blood donations serves to prevent a portion of all infections among patients. Without HEV screening, the annual number of



persons who would be infected with HEV via blood transfusions is estimated at 187. HEV screening reduces this number to 13. At present, there are no alternative safety measures to protect the recipients of blood products. Experiences from abroad and an analysis carried out by Sanquin indicate that testing only part of the blood donations leads to major logistical and operational problems. Partial testing would therefore not appear to be a safe and efficient alternative to testing all blood donations.

Cost effectiveness

The cost effectiveness of screening for HEV is surrounded by uncertainties. Most probably, its cost effectiveness does not comply with commonly applied reference values for the cost effectiveness of preventive interventions (such as € 20,000 or € 80,000 per quality-adjusted life year). However, an assessment framework for cost-effectiveness in the blood supply sector is lacking, and HEV screening does not compare unfavourably to other safety measures applied

in this sector. HEV is much more prevalent than other diseases for which blood donations are screened. Of the 1.5 million blood donations tested in 2013-2014 by Sanquin, 9 donations turned out to be infected with HIV, 11 with hepatitis C virus, and 25 with hepatitis B virus, whereas an estimated 1920 donations were infected with HEV.

Recommendations

The Committee advises to continue testing all blood donations for HEV for the time being. Blood donors are frequently infected with the virus, and persons receiving blood products often have a weakened immune system, as a result of which an HEV infection can have a serious outcome. The cost effectiveness of HEV screening does not compare unfavourably to other safety measures in the blood supply sector. The Committee sees no reason to set cost effectiveness requirements for HEV NAT screening that do not apply to other safety measures in the blood supply sector. The Committee does recommend developing an

assessment framework for cost effectiveness in the blood supply sector by means of which the costs of safety measures can be taken into account in a consistent and unequivocal manner. The Committee also recommends investigating which measures can be taken in the food chain. Finally, the Committee advises to reassess the importance of HEV screening when additional research has been carried out into the dynamics of the number of infections among blood donors, into the probability of infection at low concentrations of virus particles in blood products, and into the disease burden and treatability of HEV for various patient groups.



The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity. The reports are available to the public.

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