Is viral nucleic acid testing of eye donors cost-effective?

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To the Editor: The Therapeutic Goods Association (TGA) has informed Australian eye banks that nucleic acid testing (NAT) of donor sera will be required in addition to routine serological tests for hepatitis B virus (HBV), hepatitis C virus (HCV) and HIV. NAT can detect viral genome in the window period between infection and the appearance of antigen or antibody, and is to commence in Australia as soon as possible. However, we believe the benefit of NAT would be small and the cost considerable. Importantly, it would be likely to have an adverse effect on the availability of donor corneas for transplantation.

HBV, HCV or HIV have not been transmitted from seronegative donors by means of corneal transplantation. In the mid 1980s, HBV was almost certainly transmitted by corneal tissue to two recipients in the United States who developed acute hepatitis B; HBV surface antigen was detected subsequently in the donor sera.[1] The transmission of HCV or HIV has not been reported despite corneal transplantation from infected donors.[2,3] The American Red Cross instigated HCV/HIV (but not HBV) NAT for blood donors in 1999, and the US Food and Drug Administration mandated HCV/HIV NAT for eye donors in 2007.

So, how many window-period eye donors could be identified by NAT? It has been estimated that 7.2 per 100 000 American tissue donors are in this period for HBV, HCV or HIV.[4] With NAT, the number reduced to 1.8 per 100 000 (most assays, including NAT, have sensitivity limitations). Let us assume that the prevalences of HBV and HCV are the same in Australia and the US, the prevalence of HIV in Australia is half that of the US, and that prescreening by medical and social history is equally effective in both countries. At 700 corneal donors (1200 grafts) per year in Australia, one window-period donor would be expected every 23 years, falling to one every 93 years with NAT. Thus, one window-period donor would be detected by NAT every 30 years at an estimated cost of $9 million ($50 per donor averaged up for out-of-hours testing and kit wastage) plus any charges for specimen transport. If only HCV/HIV NAT is performed, such a donor would be detected every 52 years.

What is the actual risk of infection? Assuming 25 000 corneal donors (43 000 grafts) per year in the US, the figures[4] suggest that eyes were collected from one window-period donor every 7 months between 1990 (when a serological test for HCV became available) and 2007, but no infections have been reported. Perhaps there was no virus in the corneal tissue; even among donors who are seropositive for HBV, HCV or HIV, few have detectable viral genome in the cornea.[5,6] It is not known whether these viruses can invade the cornea before the appearance of antibody, but the risk that infection will occur in recipients of corneas from HCV/HIV-seronegative, NAT-positive donors appears to be very small indeed.

The TGA's decision may have been based on factors other than this type of analysis. We believe the decision should be reconsidered.

Competing interests: Paul Badenoch is the Quality Control Officer and Douglas Coster is the Medical Director of the Eye Bank of South Australia.

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