

BACKGROUND NOTE FROM THE CHIEF MEDICAL OFFICER

SCREENING BLOOD DONATIONS FOR HTLV III ANTIBODY

This note gives the background to today's announcement by the Minister for Health that a screening test for antibodies to HTLV III will be introduced within the next few months. Ministers have accepted that all blood donations should be screened for HTLV III antibody in order to give further assurance of the safety of blood transfusion and blood products. Evaluation of the various available tests is going ahead urgently with the intention of introducing testing throughout the Blood Transfusion Service as soon as possible. It is intended simultaneously to make diagnostic testing available through STD clinics. The PHLS is being funded to provide laboratory facilities for these tests.

More than two million blood donations are collected each year and it is clearly essential to ensure that any tests introduced on this scale must be known to give consistent results and be specific and sensitive. Specificity in this context means that a test which does not give rise to an unacceptable number of false positives each of which would require extensive further investigation and would waste the blood donations involved. Sensitivity is also of paramount importance in order that no genuine positives should be missed.

While the commercial products already on sale have been evaluated elsewhere on an individual basis no comparative evaluation is available. This requires that their performance should be compared against a single carefully chosen panel of sera and that the tests should be conducted under controlled conditions. The PHLS are currently conducting such an evaluation. A field trial designed to explore both the specificity of the test and the operational aspects of its routine use throughout the country is also essential. Ease of use and consistency in large scale screening are prime requirements in selecting a suitable product for use in screening blood donations. Laboratory and field evaluations, both undertaken on a large scale, will enable an informed choice to be made and will promote confidence in those kits which are subsequently chosen.

When screening is introduced into the Blood Transfusion Service those donors who are found to be genuinely positive following confirmatory testing will be informed so that they can be referred for counselling. Arrangements are being put in hand to provide this service. It is expected that the numbers who are detected as positive will be very small indeed.

The present policy of Regional Transfusion Centres is to dissuade people in high risk groups for AIDS from volunteering to give blood and this will continue after the introduction of screening. Alternative facilities will be provided to enable those in high risk groups to obtain tests and counselling.

It has been suggested that testing should be introduced immediately, before the reliability of the tests available has been evaluated. Early experience of other countries and the considerations outlined in this note have led Ministers to decide that it would be wrong to introduce a screening test until the further evaluations mentioned above have been carried out.