For Action: Dr Epsley, Ms Cunliffe
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To: NHS Trust Medical Directors

cc: NHS Trust Chief Executives
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PL (CO) (98) 1

Dear Colleague,

NEW VARIANT CJD - PATIENTS WHO HAVE RECEIVED IMPLICATED BLOOD PRODUCTS

In September 1997 the Chief Medical Officer announced that the use made of blood donated by persons who had subsequently developed new variant Creutzfeld Jacob disease (nvCJD) would be traced and, as a purely precautionary measure, any unused blood components or products withdrawn. As a consequence, there have been a number of recall exercises over recent months, the latest being the batch of Amerscan Pulmonate Two which was withdrawn in December.

A number of clinicians and Trusts affected by these recall exercises have contacted the Department of Health to ask for the Department's view on what patients who have received nvCJD-implicated blood components or products should be told. This raises some very difficult issues on which the Department has taken expert ethical advice. I thought it might be helpful to set out that advice.

The advice which the Department has received from ethics experts and other advisory bodies is that there is no need to inform patients because:

i. it is thought unlikely that nvCJD will be transmitted in this way;
ii. there is no diagnostic test for nvCJD;
iii. even if a test was available, there is no preventative treatment that could be offered.

In these circumstances the general view is that patients will not benefit from this knowledge, and that uncertainty created by informing patients could have the contrary effect causing unjustified worry and creating a permanent blight on their lives in relation, for example, to obtaining life or health care insurance.

The local Ethics Committee that advises the CJD Surveillance Unit reached the same view when considering whether to inform patients included in the epidemiological study.

In deciding whether or not to inform a particular patient, the benefit/harm balance for their individual situation must be carefully considered. In communicating with patients who have received implicated products, it is therefore for individual clinicians to decide whether to follow this general ethical advice.

There may clearly be some circumstances where clinicians will decide to inform a particular patient of the reason for the product withdrawal, for example where a product involved in the recall is one that is generally held by the patient at home, or where the recall action has prompted an individual patient specifically to ask whether he/she has received the implicated blood product. In such circumstances it is for the clinician to decide how best to respond, having taken careful consideration of all aspects of his/her patients circumstances.

It should be noted that this ethical advice reflects current circumstances and knowledge and will be kept under regular review in the light of scientific advances and the advice of national and international committees.

GRO-C

DR GRAHAM WINYARD
DIRECTOR
HEALTH SERVICES