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Dr John D Cash
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Dear John

FACTOR VIII CONCENTRATE : PLASMA QUALITY

As I think you are aware I have spent most of this week carrying out investigations into areas of function of the PFC where performance is less than to my satisfaction. One of these was investigation of the fact that, in recent time, too many pools of factor VIII have required large volume fillings because of low yield at the bulk stage. Since there is still some uncertainty in the yield to be expected from any particular batch we operate a system whereby an assay is done on the final bulk product immediately before the last sterile filtration and the fill volume is calculated from this assay. In essence, if the activity concentrate is 7 units per ml or higher the product is filled in a vial to yield a theoretical 250 unit dose. If the concentrate is lower than 7 units per ml at this stage it is filled in a bottle at a volume to provide roughly 250 units in a dose of variable volume larger than 20 ml. There have been too many of the latter in recent time for my peace of mind and this suggests that there have been abnormal losses during process.

On investigation I have discovered that the major factor appears to be low levels of factor VIII present in the starting plasma and, from past experience, we have noticed that a pool containing a significant proportion of plasma having low factor VIII concentration also results in lower than average yield on a percentage basis.

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We collect, at random, plug samples from the frozen packs and have these assayed for factor VIII content along with samples from the frozen pool and from the thawed pool. The last two are truly of little value since they are, of necessity, taken from an uneven mixture situation. I enclose for your interest the assays recovered from the last batch processed for which assay is complete. You will notice that with one notable exception the measured value is substantially lower than the estimated value and the preliminary estimate of the total recovery from this pool is only 30%.

This plasma is all of the 18 hour old variety but should have been 0.7 units per ml or thereabout and is too low for easy recovery. I accept immediately that the method of recovery which we use is unsatisfactory but it is about the best around at the moment and, if one accepts that, it is necessary to try harder at the collection end. Both Aberdeen and Dundee have done better in the past and I would be interested to have your advice as to how we can point out, gently, that the present is not good enough.

With kindest regards

Yours sincerely

JOHN G WATT
Scientific Director