ABSTRACT FORM ECAT SYMPOSIUM 8 – 9 NOVEMBER 2018

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Title:

Quality Assurance of Extended Half Life Products

Abstract:

Extended half-life (EHL) products offer advantages to people with haemophilia, with respect to frequency of treatment and improved trough levels of FVIII and FIX. However, measurement and treatment monitoring of these products has been shown to be a challenge to the haemostasis laboratory. Published data have shown marked variability in recovery of protein levels in plasma using different assay methods or reagents. However, many of these studies have been single centre studies, and often fail to capture the full range of methods routinely employed in laboratories. External Quality Assurance exercises, in which the same material is sent to large numbers of centres to perform the same assay for treatment monitoring, can identify the degree of agreement between centres, and act as an effective field study for new and existing products.

EQA studies published to date have demonstrated method and reagent-specific differences in recovery of FVIII levels for both standard and extended half-life products. A recent, collaborative exercise between the UK NEQAS, ECAT and RCPAQAP proficiency testing programmes allowed for collection of data from a larger number of centres monitoring FIX levels post treatment, and showed marked differences in samples containing 'trough' levels of drug (6 IU/dL) and 'post-treatment' levels of drug (60 IU/dL). With some reagents, more than 20-fold differences in measured level compared to expected recovery were observed. These findings echo those reported in smaller studies – and are particularly important as these methods are those in routine treatment-monitoring use in laboratories at the current time. Such differences could have profound clinical consequences, and underline the importance of communication between clinic and laboratory to ensure appropriate methods are employed to monitor factor therapy.