**Generic ciclosporin: supervised switch programme for renal transplant recipients from Neoral-ciclosporin to Vanquoral-ciclosporin: Interim analysis**

Background: Generic ciclosporin (CyA) is not new to the market. However previous brands did not meet the revised European Medicines Agency (EMA) drug bioequivalence guideline for narrow therapeutic index drugs which have applied from 2010. Vanquoral-ciclosporin by Teva does meet the tightened bioequivalence acceptance interval. The Oxford Transplant Centre commenced in March 2017 a pharmacy led supervised switch programme for all renal transplant recipients on Neoral-ciclosporin regimes, as part of a cost improvement initiative.

Method: Renal transplant patients taking Neoral-ciclosporin based immunosuppression were identified via electronic records. All transplant related medicines are supplied by Transplant Centre. Patient’s received a letter describing the generic ciclosporin switch programme, with explanation it was an NHS cost saving initiative. Neoral patients were identified on clinic lists and, where possible, met with project nurse in advance of seeing the clinician or pharmacist. With patient agreement, Vanquoral was then prescribed, a switch check list provided and advice given to use up existing Neoral stock. Once Vanquoral commenced, patient notified us (email/telephone): date of switch and date of “check” CyA level (2-5 weeks after switching) so ensuring level was reviewed. All patient data was recorded on a secure, password protected electronic database. Up to 5 pre-switch CyA and creatinine (Cr) levels were recorded in addition to prospective levels post switching. Variability in ciclosporin levels pre and post switch were evaluated.

Results: A total of 157 Neoral patients were identified. 5 patients were on Neoral liquid so were excluded. 15 patients were not switched for various reasons – clinically unstable n=4, social situation n=4, patient refusal n=2, moving out of area n=3, already on generic n=2. Three patient deaths occurred during the switch period (had not switched to generic).

89/130 (68%) patients had been switched as of 1/9/17. There have been no adverse reactions, no noticeable difference in serum creatinine or ciclosporin levels compared to baseline. No rejection episodes occurred. Only 2/89 (2%) required small ciclosporin dose change after switch. One patient requested a switch back to Neoral due to non-specific vague symptoms.

Conclusion: Preliminary results and clinical impression of this supervised generic ciclosporin switch programme have not demonstrated any safety concerns. The post-switch level was a precautionary measure and offered reassurance to patients that they were being switched in a controlled environment. The cost efficiency savings generated will be reinvested back into clinical services to further enhance quality of care.

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