Healthcare Improvement Scotland

NICE Health Technology Appraisal - Assessment Report On Kidney transplantation (adults) - immunosuppressive therapy (Review of TA 85)	
TO: NICE **Friday 08 2015**	**FROM: Healthcare Improvement Scotland**

Comments provided to Healthcare Improvement Scotland by:
[redacted], [redacted].

This report is a carefully conducted and wide ranging review and analysis of immunosuppression in kidney transplantation in the UK. The ultimate conclusion endorses the current common practice in the UK that standard immunosuppression should involve the use of induction with Basiliximab and maintenance immunosuppression with tacrolimus and mycophenolate.

The rest of the report is of limited value. An exercise has been conducted based on clinical trials, of which there are relatively few, none of which have the quality normally expected of clinical trials in the NICE analyses. The authors acknowledge this fact, which is well recognised. The FDA have quite recently had a summit which recognised the failure of existing end points in clinical trial of renal transplantation.
The authors do not recognise some flaws in trials that limit interpretation. For example the CsA dose and levels in the Belatacept trials (BENEFIT, BENEFIT-ext) are high, and likely to be associated with poor graft function and therefore any apparent improved graft functions in these trials may not be relevant is not relevant. Moreover, graft function with Belatacept is no better than that one sees with MMF and Tac in clinical practice.
I do not understand the decision to exclude malignancy in the long term outcomes given that this is the leading cause of death in renal transplant recipients and most immunosuppressive agents increase the risk of malignancy. The lack of data on CV disease is a limitation, although post transplant diabetes is included. The analysis is limited to short term follow up, reflecting the paucity of long term data (except in Registries), in clinical trials.
The most important omission is of Registry data which shows improving outcomes despite increasing comorbidity and immunological risk, which might usefully have been combined with the analyses performed to make practical recommendations..
Overall, despite the above caveats, the findings in favour of Basiliximab, with MMF and Tacrolimus as the best immunosuppressive strategy fit with current clinical practice and support the practical view of most transplant clinicians.