BRITISH TRANSPLANTATION SOCIETY RESPONSE TO:

Multiple Technology Appraisal (MTA)

Immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85) [ID456]

Thank you for inviting the British Transplantation Society (BTS) to contribute to this consultation. This response is submitted by the Executive on behalf of the BTS Council.

The Council agrees with the overall conclusion of the appraisal that triple therapy combining Basiliximab, Tacrolimus and Mycophenolate Mofetil is the optimal immunosuppression regimen.

Other options such as Belatacept, Antithymocyte globulin (ATG), Everolimus and Sirolimus should only be used for specific indications and funded by the NHS on a named patient basis or as part of a clinical trial.

An analysis of higher potency regimens or triple maintenance therapy for patients at higher immune risk (e.g. those with high panel reactive antibody/calculated reaction frequency; vascular rejection; antibody mediated rejection; repeat transplantation) would have been of value.

Statistical Analysis

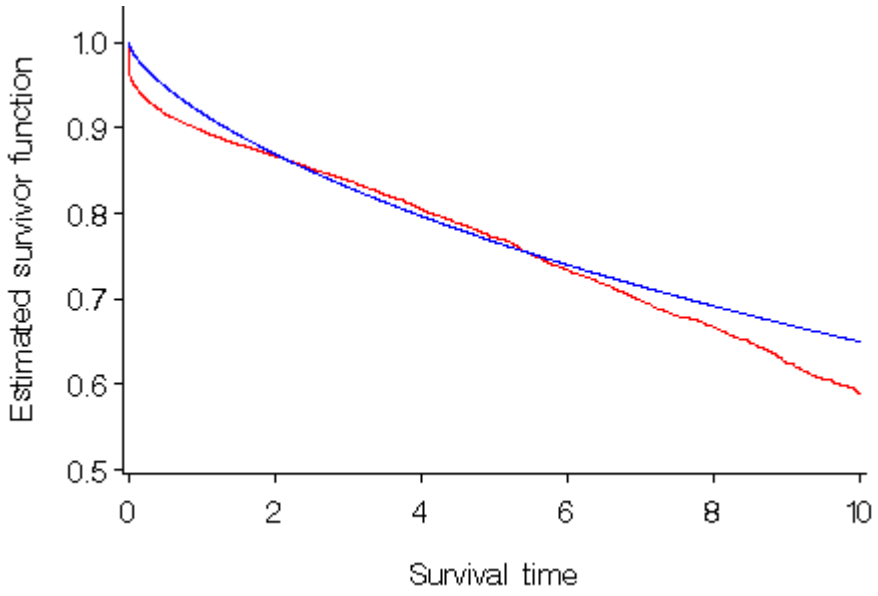
The Department of Statistics and Clinical Studies at NHS Blood and Transplant, had specific concerns about the validity of the statistical model applied in the appraisal i.e. the Weibull model for survival, conditional on survival to one year, for the following reasons:

- It is argued that the Cox Snell residuals indicate no problem, but this is not considered to be a good way to validate the fit.

- In general, their experience has shown that the Weibull is not a good fit for post transplant outcome, as it tends to level off more slowly than survival data suggest. Example (Figure 1) included showing Weibull fit (blue) and Kaplan-Meier estimate (red) for kidney transplant outcomes, starting at transplant rather than one year on.

- Use of the Weibull model could lead to higher predicted survival rates and higher medians. Fig 92 suggests a median graft survival of over 25 years, which seems rather high. The figures in Table 162 look more realistic, perhaps because the fit is better in shorter time periods.

Figure 1.



Summary

This appraisal, typically, focused upon the cost effectiveness of immunosuppressive therapy for adult kidney transplantation. The assessment included an extensive review of Randomised Controlled Trials, which may not reflect 'real life' nor the diversity and complexity of the clinical case-mix. Other regimens may, therefore, be required for certain patient groups.