

012 THE UK MS RISK-SHARING SCHEME: RESULTS FOR YEARS 4 AND 6

Martin Duddy,¹ Jacqueline Palace,² Thomas Bregenzer,³ Helen Tremlett,⁴ Feng Zhu,⁴ Mike Boggild,⁵ Kate Tilling,⁶ Yoav Ben-Shlomo,⁷ Charles Dobson⁸. ¹Royal Victoria Infirmary, Newcastle upon Tyne; ²Radcliffe Infirmary, Oxford; ³PAREXEL, Berlin, Germany; ⁴University of British Columbia, Vancouver, Canada; ⁵Townsville Hospital, Queensland, Australia; ⁶Department of Social Medicine, Bristol University; ⁷School of Social and Community Medicine, Bristol University; ⁸Department of Health, UK

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Following guidance from NICE in 2002, the Risk-sharing Scheme (RSS) was established to ensure cost-effective provision

of interferon-beta and glatiramer acetate in the UK. The aim was to permit price adjustment should prospectively collected disability data deviate from the predicted course of treated patients modelled from natural history data.

The first analysis identified problems with both the modelling and the chosen natural history dataset, resulting in estimations of the treatment effect which lacked validity and were not robust to sensitivity analyses.

Guided by a Scientific Advisory Group blinded to subsequent data, a new analysis plan was derived, identifying the British Columbia MS database as a better comparator, and adopting a continuous Markov model with a single covariate. An alternative repeated measures model was developed in parallel. A series of sensitivity analyses were agreed.

The predicted course of the RSS cohort on and off treatment has been modelled to 6 years from baseline values using both methods and compared to the observed data. Sensitivity analyses to examine the impact of assumptions in the analysis plan have been performed. The calculated deviation scores demonstrate how the drugs have performed in the real world compared to predictions from the short term randomised trials.