

## Flexible modelling of exposure effect in the self controlled case series method

Yonas Ghebremichael-Weldeselassie

The Open University, UK

The self-controlled case-series method (SCCS), commonly used to investigate potential associations between vaccines and adverse events, requires information on cases only and automatically controls all age-independent multiplicative confounders, while allowing for an age dependent baseline incidence.

Currently the SCCS method represents the time-varying exposures using step function. However, using step functions are associated with problems of discontinuities in risks at category cut points, not being biologically plausible and violating the assumption of actual risks varying smoothly with data. Moreover, misspecification of categories may lead to biased results. We therefore, propose to model exposure effects using flexible functions. We represented time since exposure using a linear combination of cubic M-splines. The use of M-splines in addition to giving plausible shapes it avoids the integral in the log likelihood function of SCCS method.

The new approach is validated in simulations and applied to investigate the association between the risk of fractures and exposure to Thiazolidinediones. The simulation study showed that the new approach performs better.

### Biography

Yonas Ghebremichael-Weldeselassie is in his last year of Ph.D. study at the Open University, Milton Keynes, UK. He completed his MSc in Biostatistics in 2010, from Hasselt University, Belgium, with great distinction in the first year and distinction in the second year of study. He gave an invited talk at the 33rd conference of the International Society for Clinical Biostatistics and contributed talks in other conferences. From his Ph.D. project, Yonas has so far published one paper in and submitted another to reputed journals

[Yonas.Weldeselassie@open.ac.uk](mailto:Yonas.Weldeselassie@open.ac.uk)