Introduction

Previous validation studies of the IMS CORE Diabetes Model (CDM) (1-2) have confirmed the model as a credible tool for predicting both the absolute number of clinical events and future treatment consequences associated with the management of diabetes patients.

The CDM has recently undergone a single all-cause mortality (ACM) validation exercise including internal validation and external validation against a number of contemporary outcome studies (3-5) which has been shown to provide accurate estimates of mortality risk for patients with T1DM or T2DM. A total of 37 validation end-points were reproduced in the CDM and projected over 10 year ACM predictions from the CDM.

In this study, the model compared to contemporary outcome studies such as ACCORD, ADVANCE, ADVAD and ASPEN in which mortality incidence was notably low. It is generally understood that these studies reported low mortality incidence, likely because patients were managed under controlled clinical trial (RCT) conditions. As the external validation of diabetes simulation models is in the predict the implications of new technologies in clinical practice, the above findings were compared to a number data sources are not realistic.

It is important to acknowledge that expectations towards universal valid models that match arbitrarily selected external data sources are not realistic. Model validations must be regarded in context and should include a broad range of diabetes patients to enable assessment of the models predictive ability.

This validation exercise outlines the observed discrepancy when the CDM is compared from data RCTs or to data from non-controlled, real-world observations.

In concluding, mortality was generally underestimated in projections UK82 and UK68. This trend increased with age and rising co-morbidity level.

GPRD validations demonstrated a more balanced picture with ACM being overestimated in two glucose lowering regimens (MET, MET+SU), underestimated in two regimens (SUL, MET+SU) and matched for MET+INS.

The CCM closely reflected the trends of the WA-LEC with UK82 RE. The overall ACM underestimation when compared to real-life datasets. ACM predictions of the models predictive ability.

Life expectancy calculator based on administrative data-set from Western Australia (WA-LEC)

The external validity of the CCM was tested against a life expectancy online calculator (9) that utilizes diabetes specific mortality risk equations derived from 13,646 Western Australian hospital and mortality records (10).

Life expectancy after diabetes related myocardial infarction (MI) and stroke (Re) was predicted for male and female subsets in (a) three age strata (50-60, 65-70 and 80+ years) and compared to respective predictions of the CDM.

The CDM was used under two alternative sets of risk equations (Re).

Base Case: using UKPDS 82 risk equations (Re) to assess CV and mortality risk:

SA: using UKPDS 68 RE to assess CV and mortality risk:

All cause mortality validation of the IMS CORE diabetes model against predictions of the Charlson Comorbidity Index

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