Mount Hood Diabetes Challenge 2025, Chicago

Mount Hood Obesity Challenge: SELECT Clinical Trial

Draft 18 March 2025

CIRCULATED FOR COMMENT ONLY
CHALLENGE SUBJECT TO CHANGE

This is being circulated for information and comments only – DO NOT use these instructions for the challenge.

Objective: To evaluate and compare the performance of different obesity simulation models in predicting the cardiovascular outcomes of overweight or obese patients without diabetes, based on the findings from the SELECT clinical trial.

Background: The SELECT clinical trial demonstrated that once-weekly subcutaneous semaglutide 2.4 mg significantly reduced the risk of major adverse cardiovascular events (MACE) by 20% compared to placebo in overweight or obese patients with established cardiovascular disease but without diabetes. The primary endpoint was the composite outcome of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke.

Challenge Design:

1. **Participants:**
    - Simulation modelling groups with expertise in obesity, diabetes and cardiovascular disease.
    - Each group will use their own simulation model to predict outcomes based on the SELECT trial data.
2. **Data Inputs:**
    - Baseline characteristics of the SELECT trial population:
        - Age: ≥45 years
        - BMI: ≥27 kg/m²
        - Established cardiovascular disease
        - No history of diabetes

Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2307563#ap2

3. **Simulation Tasks:**
    - Predict the incidence of MACE (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) and progression to diabetes over a 5-year and lifetime horizon (documenting relevant assumptions made on risk factor progression)
    - Estimate the reduction in risk of complications with semaglutide compared to placebo over the 5 year and lifetime horizons.
    - Report lifetime cost of complications, quality adjusted life years (QALYs) and life years (Lys) **excluding** the cost of semaglutide.

4. **Outcome Measures:**
    - Accuracy of predicted MACE and diabetes incidence compared to actual trial results.
    - Consistency of risk reduction estimates with the SELECT trial findings.

- Comparison of lifetime projections (costs, QALYs, LYs)

5. **Evaluation Criteria:**
    - Model accuracy in predicting clinical outcomes.
    - Transparency and reproducibility of model assumptions and methodologies.

6. **Reporting:**
    - Each group will submit a detailed report of their simulation methods, assumptions, and results.

Expected Outcomes:

- Enhanced understanding of the predictive capabilities of different obesity simulation models.
- Insights into the way in which costs and health utilities are applied, the choice of risk equations used, model assumptions and their impact on short and long-term model projections.
- Identification of best practices and areas for improvement in obesity simulation modelling.