Estimating Caregiver Spillovers Using Within-Trial Data for Use in Economic Evaluation

an Analysis of Caregiver EQ-5D and Epilepsy Patient Data Collected in the EPISODE Study on Seizure Dogs

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Background

Health Technology Assessment (HTA) bodies are increasingly recognizing the importance of including caregiver spillovers in reimbursement decision-making. However, examples of HTAs that incorporate within-trial caregiver data remain scarce, and methodological guidance on integrating such data into economic models is limited. Using caregiver and patient data from the EPISODE study on seizure dogs for severe refractory epilepsy, this research explores methods to predict caregiver EQ-5D utilities from parameters commonly employed in economic evaluations.

Why it matters

- **Including caregiver spillovers in economic models enables HTA assessments to better reflect the full societal impact of healthcare interventions**
- **Collecting caregiver data within-trial is generally preferred, as it reduces the uncertainty of having to rely on secondary sources.**
- **By exploring practical ways to include caregiver utilities, this work addresses a key gap in HTA methodology and hopefully will stimulate discussions on best practices.**

The EPISODE (EPIlepsy SuppOrt Dog Evaluation) study

25 patients from the Netherlands

36-month follow-up

Partnered with seizure dog in randomised order

Seizure diary and three-monthly patient + caregiver questionnaires

✓ Effective in reducing seizure frequency

✓ Cost-effective addition to standard of care

⚠ Not suitable for all patients

Beyond the patient: how caregivers benefit from seizure dogs

Methods

During the EPISODE study, 266 patient-caregiver dyad observations were collected, and utility scores were calculated using the Dutch tariff. Random-effects Tobit models were applied to individually examine predictors of caregiver EQ-5D-5L utility scores. Predictor selection was guided by hypothesised mechanisms behind spillover effects, focusing on factors related to patient outcomes, the caregiving setting, and the treatment setting. The predictive accuracy of each model was evaluated using the mean absolute prediction error (MAE) and root mean squared prediction error (RMSE).

Univariate analyses for predicting caregiver EQ-5D utilities

Patient characteristics	• EQ-5D-5L utility • Seizure frequency (primary outcome EPISODE study) • Seizure-free days
Caregiver characteristics	• Informal care hours
Treatment characteristics	• Treatment arm • Time on treatment

Results

Model performance

	Prior to seizure dog	With seizure dog	MAE , RMSE
Caregiver EQ-5D utility	0.832 (0.147)	0.861 (0.110)	N/A
Patient EQ-5D utility	0.674 (0.262)	0.748 (0.214)	0.0940, 0.1313
Seizure frequency	112.2 (161.2)	79.8 (140.0)	0.0937, 0.1345
Seizure-free days	11.7 (9.9)	15.0 (9.8)	0.0914, 0.1285
Informal care hours	22.9 (21.5)	21.9 (20.4)	0.0878, 0.1136
Treatment arm	N/A	N/A	0.0957, 0.1347
Time on treatment	N/A	N/A	0.0957, 0.1344

Key findings

- Caregivers experience a higher EQ-5D utility score after the patient is partnered with a seizure dog.
- The models predicting caregiver utility scores based on informal care hours or seizure-free days showed the highest predictive accuracy.
- Among other models analyzed, predictive accuracy varied minimally.
- The direction of impact for each predictor aligned with expectations.

Conclusions

This analysis investigates various approaches to estimating caregiver spillovers using within-trial data. Different modelling methods may yield different results, making it essential to carefully consider how such data is integrated into economic evaluations. Balancing clinical plausibility with predictive performance ensures that caregiver spillovers are both accurately and meaningfully represented.

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