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Figure 1: The distribution of EQ-5D-3L UK Tariff scores in a series of studies

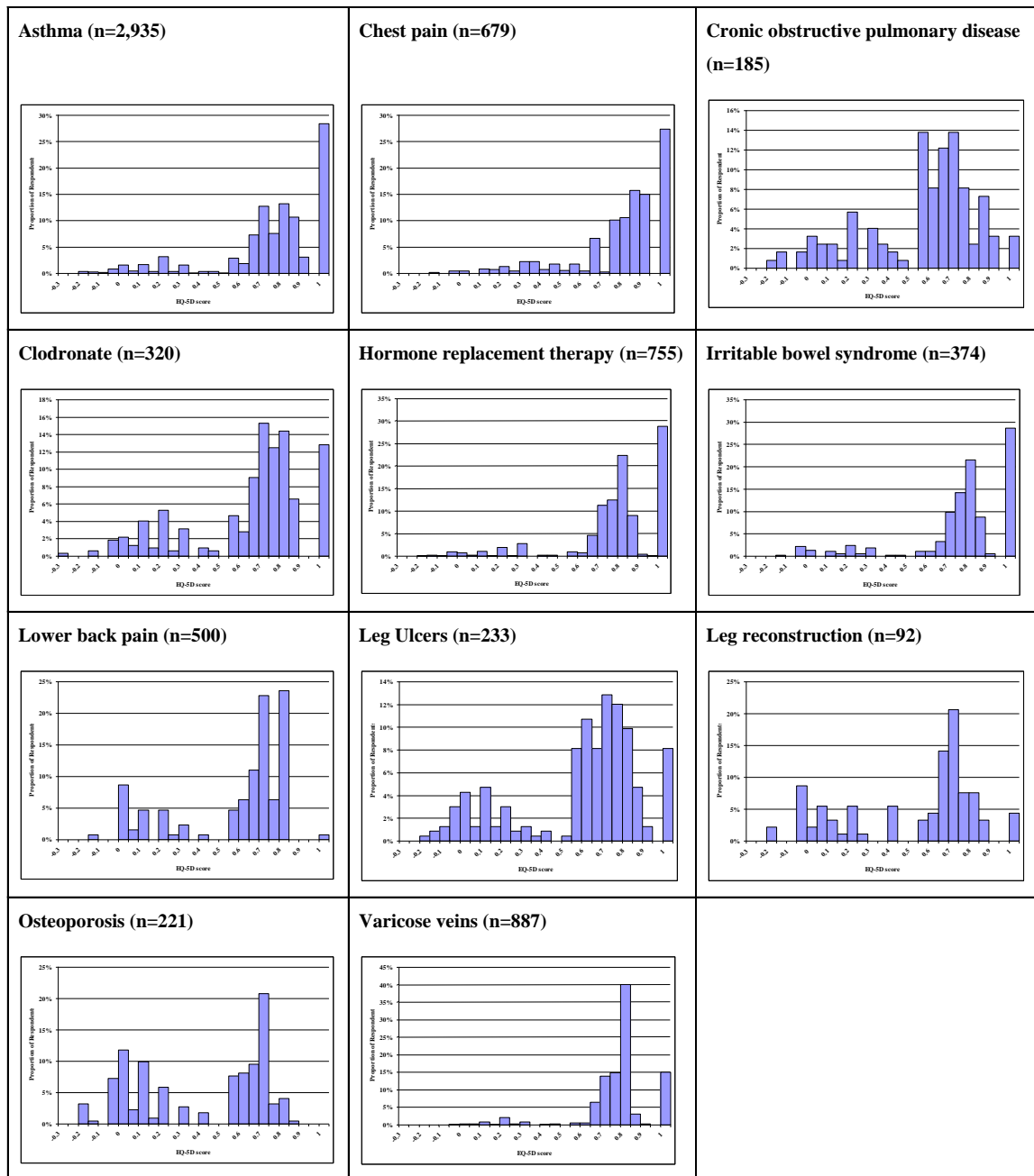


Table 1: Summary of Pre-modelling Recommendations

1. Consider the use or potential uses of the mapping:
 - a. Is it for use in a cohort decision model, patient level model or trial-based cost-effectiveness analysis?
 - b. What are the health states that require utility estimates from the mapping and how do they relate to the PBM?
 - c. What is the range of disease severity for which utility values are required?
2. Provide a descriptive account of the clinical explanatory variable, the dependent PBM and the extent to which they overlap.
3. Assess if a regression-based mapping is required.
 - a. How many health states require estimates of utility?
 - b. Are there additional covariates of importance?
 - c. Are there sufficient observations within each category?
4. Identify if more than one dataset is potentially available for estimation. Compare the characteristics of candidate datasets.
5. To what extent does the distribution of patient characteristics in the sample datasets reflect those that are the subject of the cost effectiveness analysis? In particular, are all extremes of disease severity represented?
6. Is the type of treatment a patient receives likely to influence the relationship between health utility and clinical outcome measures?

Table 2: Summary of Modelling and Data Analysis Recommendations

1. Consider whether the cost-effectiveness analysis requires a formal regression-based mapping model approach, or if it is suitable to take the mean value for sub-samples of patients.
2. If regression is required, then model selection should be based on:
 - a. Consideration of the most straightforward statistical model type whose assumptions are compatible with the target utility instrument. Use a plot of the distribution of the utility data to help inform that choice.
 - b. Existing empirical evidence of the performance of different methods. There is no reason for this to be restricted to evidence from any specific disease area.
 - c. The type of cost-effectiveness analysis where the mapping will be used and the extent to which biased estimates will affect the results.
3. For response mapping, models should be selected that respect the ordered nature of the categorical data in the descriptive system. Expected values should be calculated analytically.
4. Selection of the preferred mapping model is an iterative process that should conform to good practice common to all regression analyses.
5. Covariates should be theoretically justified a priori. Exclusion of covariates, even if they are not to be used in the cost-effectiveness model, risks mis-specification.

Table 3: Summary of Reporting of Mapping Studies Recommendations.

1. Describe relevant differences between datasets that are candidates for mapping estimation.
2. Give full details of the selected dataset. Describe how the study was run and patients were sampled. Provide baseline and follow-up characteristics including the distribution of patients' disease severity. Missingness in the longitudinal pattern of responses should be described.
3. Plot the distribution of the utility data.
4. Justify the type of model(s) selected with reference to the characteristics of the target utility distribution and the proposed use of the mapping function.
5. Compare the dimensions of health covered by the target utility instrument and those covered by the explanatory clinical measure(s).
6. Describe the approach to determining the final model. Include tests conducted and judgements made.
7. Summary measures of fit are of limited value for the total sample. Provide information on fit conditional on disease severity as measured by the clinical outcome measure(s). A plot of mean predicted versus mean observed utility conditional on the clinical variable(s) should be included.
8. Coefficient values, error term(s) distributions(s), variances and covariances are required.
9. Provide an example predicted value for some set of covariates. Consider providing a program that calculates predictions for user defined inputs.
10. Parameter uncertainty in a mapping regression should be reflected using standard methods for Probabilistic Sensitivity Analysis (PSA). Assessment of model suitability for use in cost-effectiveness analysis should also consider the distribution of utility values for PSA, with particular focus on whether these lie outside the feasible utility range for the PBM.
11. When imputing data from a mapping function, individual level variability should be incorporated using simulation methods and information about the distribution of the error term(s). These simulated data can be compared to the raw observed data, including an assessment of the range of values compared to the feasible range for the PBM.
12. Re-estimation of mapping results in a separate dataset, or other forms of validation, are not routinely required.