## Week Five - Critical appraisal exercises

CHEERS checklist

Pollock RF1, Muduma G, Valentine WJ. Evaluating the cost-effectiveness of laparoscopic adjustable gastric banding versus standard medical management in obese patients with type 2 diabetes in the UK. Diabetes Obes Metab. 2013 Feb;15(2):121-9.

| Section/item | Item No | Recommendation | Reported on Page No |
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| **Title and abstract** | | | |
| Title | 1 | Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared. | P121 |
| Explanation | | Study type: 'cost-effectiveness' in the title<br>Interventions: laparoscopic adjustable gastric banding vs. standard medical management | |
| Abstract | 2 | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | P121 |
| Explanation | | • Objectives: to evaluate the cost-effectiveness of LAGB vs. SMM in obese patients with type 2 diabetes<br>• Perspective: UK healthcare payer perspective<br>• Setting: UK<br>• Methods:<br>  ○ Study design: decision analytic modeling<br>  ○ Inputs: projected outcomes from a validated model of diabetes with follow-up data from a 2-year RCT<br>  ○ Time horizon: 40 years<br>  ○ Discount rate: 3.5% for both costs and outcomes<br>  ○ Sensitivity analysis was performed<br>• Results: LAGB vs. standard: 0.64 years increase, 0.92 QALYs, 4552 increase of | |

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| | | treatment cost. ICER: 3602 pounds per QALY<br>• Not reported: Results from uncertainty analyses in the abstract<br>• Conclusions: LAGB is likely to be considered cost-effective from the NHS perspective when compared with SMM in patients with type 2 diabetes in the UK. | |
| **Introduction** | | | |
| Background and objectives | 3 | Provide an explicit statement of the broader context for the study. | P121 |
| Explanation | | • Prevalence of obesity is increasing around the world<br>• Associations between obesity, diabetes and other conditions are well established<br>• There is a high economic burden related to obesity<br>• A NICE guideline for management of obesity introduced LAGB surgery<br>• One 2-year RCT showed comparative effectiveness of LAGB over SMM but does not have long-term or cost-effectiveness results | |
| | | Present the study question and its relevance for health policy or practice decisions. | P122 |
| Explanation | | - | |
| **Methods** | | | |
| Target population and subgroups | 4 | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | P122, 1st parag; P123, 1st parag<br>Table 1; suppl |
| Explanation | | Dixon et al. study (2008) was chosen because:<br>• It was the first to focus specially on the high-risk group of patients (BMI between 30-40kg/m2) with UK specific data<br>Swedish Obese Subjects (SOS) study for sensitivity analysis was chosen for: | |

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| | | • a higher baseline BMI which is more closely matching a 'typical' UK cohort undergoing bariatric surgery | |
| Setting and location | 5 | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | P122, parag2 |
| Explanation | | NHS | |
| Study perspective | 6 | Describe the perspective of the study and relate this to the costs being evaluated. | P122, parag2; p123, parag3, p124, parag2 |
| Explanation | | UK healthcare payer perspective.<br>The costs being evaluated are extracted from a recent cost-effectiveness analysis in the UK patients with type 2 diabetes. Drug costs were taken from the NHS Electronic Drug Tariff and a 2010 prescription cost analysis from the Health and Social Care Information Center. | |
| Comparators | 7 | Describe the interventions or strategies being compared and state why they were chosen. | P122, parag2 |
| Explanation | | • The effectiveness of Laparoscopic adjustable gastric banding has been demonstrated with increasing evidence<br>• This is compared to standard medical management, the authors did not state why they chose these two strategies but it can be inferred that the intervention of interest was compared to the most likely control group which is standard medical care. | |
| Time horizon | 8 | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | P124, parag2 |
| Explanation | | 40 years: as the baseline age was 46.9 years for a lifetime horizon | |
| Discount rate | 9 | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | P124, parag2 |
| Explanation | | 3.5% annually for costs and outcomes as recommended by NICE guideline | |

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| Choice of health outcomes | 10 | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | P122, parag4 |
| Explanation | | Long-term outcomes were modelled using the CORE Diebetes Model version 8 (CDM), a published computer simulation model of type 2 diabetes. The outcome measures are life expectancy, QALY, and cumulative incidence of diabetes-related complications. | |
| Measurement of effectiveness | 11a | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | NA |
| Explanation | | | |
| | 11b | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | |
| Explanation | | Table 1 shows various sources for the parameters, but the authors did not mention how they found or synthesized those references. | |
| Measurement and valuation of preference based outcomes | 12 | If applicable, describe the population and methods used to elicit preferences for outcomes. | P123, parag5-P124parag1 |
| Explanation | | 'Utilities were sourced primarily from the UKPDS and supplemented with type 2 diabetes-specific utilities where necessary.'<br>The CODE-2 study （European study）used a time trade-off method and a disutility of 0.0038 was associated with every BMI unit over 25kg/m2<br>To think about: Do the results from European study represent the UK population? Is the utility decrement constant for every unit change of BMI? This is related to whether a probabilistic simulation should be conducted which vary utility values in a distribution. | |
| Estimating | 13a | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research | NA |

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| resources and costs | | methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate opportunity costs. | |
| | 13b | *Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | P123, parag4 |
| *Explanation* | | *CDM model.* | |
| Currency, price date, and conversion | 14 | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate. | P123, parag5 |
| Explanation | | Inflated to 2010 GBP values using the healthcare component of the UK consumer price index, as published by the Office for National Statistics. | |
| Choice of model | 15 | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | P122, parag3 |
| Explanation | | The figure of the model was not provided, however the authors do refer to original publication which does present a figure of the model structure.<br>CDM model: a published simulation model of type 2 diabetes, a non-product specific health policy analysis tool, comprising several inter-dependent semi-Markov sub-models, each modelling the progression of a diabetes-related complication. Reference is provided. | |
| Assumptions | 16 | Describe all structural or other assumptions underpinning the decision-analytical model. | P123, parag1, 3; Table 1; p124 parag3-6 |
| Explanation | | • Duration of diabetes: mean duration of diabetes of 1 year assumed with SD of 4 months.<br>• History of atrial fibrillation | |

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| | | • History of left ventricular hypertrophy<br>• History of end-stage renal disease<br>• Pharmacy use<br>• Number of self-monitoring of blood glucose test strips<br><br>And The parameters varied in sensitivity analysis:<br><br>• Discount rate, time horizon, unit costs of all diabetes complications, costs of all LAGB complications, HbA1c, SBP and BMI benefits, SMM treatment effects, baseline BMI, effect of BMI on quality of life, relative risks of first MI, first stroke, heart failure, angina and peripheral vascular disease<br><br>A simulation was run with second-order sampling which attempts to characterize the effects of structural uncertainties in the model. | |
| Analytical methods | 17 | Describe all analytical methods supporting the evaluation. This could include methods for dealing approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty. | |
| | | Sensitivity analysis: uncertainty. (p124) | |
| Explanation | | Subgroup analysis: heterogeneity (p123, parag1) | |
| | | Not *all* analytical methods were described. | |
| **Results** | | | |
| Study parameters | 18 | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | Table 1, 2, 3 |
| | | Deterministic analysis | |
| Explanation | | Values were reported in Table 1, 2 and 3 | |
| | | Ranges were reported in ‘sensitivity analysis’ section on page 124. | |

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| Incremental costs and outcomes | 19 | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | P124 (result section); P125 Table 4 |
| Explanation | | - | |
| Characterising uncertainty | 20a | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | NA |
| | 20b | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | P125 |
| Explanation | | One-way sensitivity analysis: 'broadly insensitive to changes in individual input parameters' except for the LAGB 'worst case' scenario produced an ICER of £36,377 per QALY gained. Second-order sampling: ICER: £3,824 with wider CI. | |
| Characterising heterogeneity | 21 | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information. | NA |
| | | This was based on a predominately white Australian population. | |
| **Discussion** | | | |
| Study findings, limitations, generalisability, and current knowledge | 22 | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | P127-8 |
| Explanation | | Key findings: from the perspective of a UK healthcare payer, LAGB would be considered highly cost-effective in obese type 2 diabetes patients when compared with SMM. ICER GBP 3602 (95%CI 2168 – 5728) per QALY gained. Results are broadly insensitive to the | |

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| | | variation of key parameters.<br><br>The author compared this present study, to previous studies and the conclusions are consistent.<br><br>Limitation: 1.) post-surgical complications were not associated with decrement in HRQoL. 2.) Did not capture any explicit benefits of diabetes remission above and beyond the changes in physiological and clinical parameters observed in the Dixon et al. trial.<br><br>Generalizability: Dixon study was in Australian setting, similar to patients in the UK. Findings may not be applicable to patients of different ethnic and clinical characteristics. | |
| **Other** | | | |
| Source of funding | 23 | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support. | P128 Acknowledgements |
| Explanation | | The study was funded by an unrestricted grant from Allergan. | |
| Conflicts of interest | 24 | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | P128 – Conflict of interest |
| Explanation | | Two of the three authors acknowledged that they received consulting fees from the manufacturer of the LAGB product. | |