Question on notice no. 270

Portfolio question number: SQ18-000696

2018-19 Budget estimates

Community Affairs Committee, Health Portfolio

Senator Stirling Griff: asked the Department of Health on 30 May 2018—

In the Homeopathy Review:

(a) Changes were made to the originally agreed research protocol after the reviewer (Optum) had already retrieved and assessed the evidence in March 2013. For example, the 'adapted GRADE' tool was developed in May 2013 and the '150' sample size and 5/5 Jadad quality trial exclusion thresholds were decided in mid July 2013. What was the quantitative impact of these changes on the Review's findings?

(b) An 'adapted GRADE' method was specifically developed but no information appears to be available showing the calculations that were used. Please provide this information.

(c) How were results aggregated across multiple outcomes within a trial to form a conclusion that the trial 'did not detect a difference', particularly since the systematic reviews inconsistently and incompletely reported primary trial outcomes? Similarly, how were meta-analytical findings incorporated with those from individual studies?

Answer —

Please see the attached answer.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2018 - 2019, 29 & 30 May 2018

Ref No: SQ18-000696

OUTCOME: 1 - Health System Policy, Design and Innovation

Topic: Homeopathy Review

Type of Question: Written Question on Notice

Senator: Stirling Griff

Question:

In the Homeopathy Review:
a) Changes were made to the originally agreed research protocol after the reviewer (Optum) had already retrieved and assessed the evidence in March 2013. For example, the 'adapted GRADE' tool was developed in May 2013 and the '150' sample size and 5/5 Jadad quality trial exclusion thresholds were decided in mid July 2013. What was the quantitative impact of these changes on the Review's findings?

b) An 'adapted GRADE' method was specifically developed but no information appears to be available showing the calculations that were used. Please provide this information.

c) How were results aggregated across multiple outcomes within a trial to form a conclusion that the trial 'did not detect a difference', particularly since the systematic reviews inconsistently and incompletely reported primary trial outcomes? Similarly, how were meta-analytical findings incorporated with those from individual studies?

Answer:

a) At the time this work was underway there was no relevant guidance or standard endorsed by NHMRC, or a relevant international organisation, on the development and content of evidence statements. As such Optum, in consultation with the Homeopathy Working Committee, developed a guidance document for drafting evidence statements (Appendix C of the Overview Report). This document was drafted over a number of months following the completion of the overview search for literature. The criteria reflect the discussions and agreement of the HWC members on the key features of the evidence base that should be captured in each evidence statement.

The only quantitative impact of these changes to the guidance document from May 2013 is that the definition of a *small trial* was revised from '51 to 199 participants' to "50 to 149 participants". This saw an additional 11 studies regarded to be of a medium size.

The revision process mainly served to provide more detail on how the body of evidence was considered in formulating evidence statements and conclusions in the Overview Report.

b) The guidance document (Appendix C) is based on the *elements* GRADE considers in drafting evidence statements; i.e. a description of the body of evidence; the level of confidence in that evidence; and a conclusion. As such GRADE tables were not used in this review but a narrative is provided in the results for each clinical condition under the heading of '*evidence statement'*.

c) As stated in Appendix C of the Overview Report:

> *The conclusions were generally based on whether or not any statistically significant findings were reported for any outcome (unless the HWC determined that the outcome had no clinical relevance). The evidence reviewer and HWC acknowledge that the assessment of 'effectiveness' based on statistical significance and not clinical significance is not ideal. This was, however, necessary due to the poor reporting (e.g. no reporting of primary outcomes, effect estimates or confidence intervals) and lack of analyses by the included systematic reviews and primary studies. Further, it was not possible to create a hierarchy of clinically relevant outcomes prior to conducting the overview (due to the number of conditions and systematic reviews included in the overview), and making post hoc decisions about the importance of outcomes is likely to be subject to bias.*

In theory, the results of meta-analyses would have been discussed when considering the body of the evidence. However, the evidence reviewer and the HWC considered that all of the meta-analyses for specific conditions (i.e. those that had the potential to be included in evidence statements) had included studies that were of poor methodological quality/had a high risk of bias. A decision was made by the HWC to state the findings of studies that were of good methodological quality and sufficient size in favour of meta-analyses that included poor quality studies.