Final report N65

Workshop: Mapping current usage of Health Economics Analysis Plans (HEAPs)

Study team:

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Original objectives

- To hold a workshop in which the extent of variation in the current implementation of health economic analysis plans (HEAPs) could be discussed and recorded.
- To map current practice and beliefs about the appropriate implementation (or otherwise) of HEAPs, with a view to drawing up good practice guidelines in future work to place HEAPs on a similar methodological footing as statistical analysis plans (SAPs).

What was achieved

- On 20 October 2015, a workshop was held in Bristol to discuss issues associated with HEAPs. 50 participants, who were mainly academic health economists, heard a range of presentations before breaking into smaller groups for discussion sessions.
- Presentations from speakers included accounts of practical experiences of using HEAPs in RCTs (Professor Dyfrig Hughes, Dr Padraig Dixon and Dr Borislava Mihaylova). Perspectives from SAP guidelines (Professor Carrol Gamble), from NICE (Ross Maconachie) and from wider economics (Professor Will Hollingworth) were also covered.
- Smaller groups were convened for discussion sessions, including a debate on the appropriate content of HEAPs. This highlighted the range of opinions and the need to achieve consensus. Discussion groups also considered the role of oversight and governance of HEAPs and potential changes to HEAPs.
- The workshop provided a forum in which issues concerning the advantages and disadvantages of HEAPs could be discussed amongst practising health economists and other interested parties. The majority of health economists present considered that constructing a HEAP has some merits in trial-based economic evaluations. However, there was agreement that HEAPs should not necessarily be followed without flexibility, and there was substantial appetite for further guidance.
- Existing guidelines in producing HEAPs were requested from participants prior to the workshop. As anticipated, this confirmed that guidance on preparing HEAPs for RCTs, and their appropriate content, is currently extremely sparse. At the time of the

workshop, HEAPs included variable content, and may or may not have been scrutinised by trial steering committees.

- Although we initially planned to produce a peer-reviewed descriptive account of the current state of health economic analysis plans based on the discussions held at the workshop, the workshop raised many more questions. We felt that the publication would be stronger with the addition of some further work on establishing best practice for HEAPs. We therefore decided to concentrate on securing funds to develop the work further, and disseminating insights from the workshop through conference presentations.
- The workshop was well timed, with the proposed content meeting a substantial research need as evidenced by the capacity audience of 50 participants (a 100% attendance rate was achieved). Feedback from the workshop confirmed that the day was considered useful by delegates, and that the organisation was good/excellent.

Outputs and examples of impact

- Slides from the workshop were disseminated via the ConDuCT-II website (https://www.bristol.ac.uk/population-health-sciences/centres/conduct2/events/past-events/heaps-workshop/)
- Insights gained from the workshop and preparative work were presented at the ISPOR 19th Annual European Congress, Vienna (November 2016) to a mixed academic and pharmaceutical industry audience (*Value in Health* 19(7) A397).
- Work was also presented at the 4th International Clinical Trials Methodology Conference (ICTMC) and the 38th Annual Meeting of the Society for Clinical Trials, Liverpool (May 2017) to a primarily trials methodology audience (*Trials*, 18(Suppl 1):P144).
- An application to extend the work by conducting a Delphi survey to identify the key content for a HEAP was submitted to the HTMR in December 2016 and funded to start in June 2017.
- A collaboration with other health economists (Warwick/Oxford) working in a similar area was developed at the Liverpool conference, allowing the project to benefit from a broader contribution to developing future guidance.
- MRC HTMR funding was acknowledged in all research outputs.

Next steps

- The extension work is now well under way. An international panel of experts has been recruited, and the first round of the Delphi survey has been completed. A second round will commence shortly, and a publication will be prepared for peer review.
- On completion of the Delphi survey, an entry for the HTMR Guidance Pack website will also be prepared.