

## **Final report N91: Health Economics Analysis Plans: developing content guidance through consensus**

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### **Original objectives**

- To identify the key content for a health economics analysis plan (HEAP) that will guide analysts in conducting economic evaluations alongside randomised controlled trials.
- To develop a HEAP template for health economists to use in trials.

### **What was achieved**

- Current examples of HEAPs were solicited from practising health economists via the Health Economists' Study Group (HESG) mailing list, and a 'long list' of 72 potential HEAP items was extracted.
- Health economists with experience of working on trials in the UK were recruited to an expert Delphi panel in order to obtain a consensus opinion on a minimum set of items for a HEAP.
- An electronic Delphi survey was developed, in which participants were asked to rate each of the 72 items on a scale of 1 (not important in a HEAP) to 9 (very important); additional items that may have been missed from the long list were also requested.
- 62 participants completed round 1 of the Delphi survey, and over 75% of these completed round 2 (48/62). The full list of 72 items was presented to participants in both rounds, with feedback from the first round reported in the second round to assist with decision making. Good agreement between participants was observed following round 2.
- A final item selection meeting was held to scrutinise the results and adjudicate on items for which consensus had not been reached. Meeting attendees included the original project team, collaborators, representatives of the Delphi participants and clinical trials unit (CTU) representatives.

- Following the Delphi survey and final discussions, a list of 58 essential items for a HEAP was derived, covering administrative details, trial particulars, details of the economic approach (including data collection, management and analysis), modelling approaches and reporting aspects. A further 9 items were assigned to an 'optional' list that researchers could consider including in a HEAP.
- A collaboration with other health economists working in a similar area was developed at the 4th International Clinical Trials Methodology Conference (ICTMC) and the 38th Annual Meeting of the Society for Clinical Trials, Liverpool (May 2017). Subsequently, Dr Melina Dritsaki (University of Oxford) and Professor Stavros Petrou (University of Warwick) were invited to join the study team, allowing the study to benefit from additional expertise.
- A survey of CTUs (led by Melina Dritsaki) was carried out to assess how HEAPs are currently used, finding that CTUs lack consistency in their approach towards HEAPs.

### Outputs and examples of impact

- A full report of the Delphi survey results was discussed at the Health Economists' Study Group (HESG) meeting in Bristol, June 2018.
- An organised session was held at the European Health Economics Association (EUHEA) conference in Maastricht, July 2018. Included talks covered the results of the Delphi survey, integration of HEAPs into standard practice and the experiences of two users of the draft HEAP template.
- Results of the Delphi survey were disseminated by means of a presentation to the Glasgow Health Economics and Health Technology Assessment group in June 2018.
- A publication describing the results of the Delphi survey is currently being prepared for submission to *Value in Health*.
- Results of the survey of clinical trials units (led by Melina Dritsaki) were published in *PharmacoEconomics*: Dritsaki M, Gray A, Petrou S, Dutton S, Lamb S E and Thorn J C 2018 'Current UK Practices on Health Economics Analysis Plans (HEAPs): Are We Using Heaps of Them?' *PharmacoEconomics* **36** 253–257
- A draft template has been sent on request to researchers for piloting purposes.
- MRC HTMR funding was acknowledged in all research outputs.

### Next steps

- The template is currently being piloted in a number of UK and international trials; feedback from the piloting will be used to develop an explanatory document to guide health economists in using the HEAPs template.
- The final template will be disseminated via the DIRUM database ([www.dirum.org](http://www.dirum.org)).
- An entry for the HTMR Guidance Pack website will be prepared.
- HTMR funds have been secured to hold a training workshop for early career researchers in health economics; planning for this event is scheduled to start in September 2018. The aim of the workshop is to increase the impact of the HEAPs template by ensuring that it is widely used by professional health economists working on economic evaluations alongside clinical trials.