Standing Committee on Finance and Public Administration

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

12 November 2012

Question no: 1

Topic: INQUIRY INTO MEDICARE FUNDING FOR HYPERBARIC OXYGEN TREATMENT

Type of Question: Written Question on Notice

Senator Fierravanti-Wells asked:

What would be an average timeframe and estimated cost of a suitable randomised control trial? What are the ethical, methodological and other issues associated with conducting an appropriate RCT or other trial?

Answer:

Randomised Control Trials (RCT) are considered to provide the strongest and most persuasive evidence for answering research questions about the effectiveness (both benefits and harms) of therapeutic services, because they provide the best method to control factors that may bias the outcomes.

There is no average timeframe for an RCT to be conducted, and the timeframe depends on a number of factors including:

- the nature of the condition and intervention being studied,
- the length of the ethical approval processes,
- the time it takes to recruit an adequate number of patients,
- the time it takes to analyse the data and prepare for peer reviewed publication,
- the length of time required to follow up patients dependent on the health outcomes to be measured.

There are some clinical scenarios where it is unethical to perform a RCT. For instance, ethics approval would not be granted for trials of treatments that have already been proven to be beneficial.

Other study designs are available to researchers in the event that an RCT is not appropriate. However, these are regarded as lower level evidence and hence less persuasive.

The HBOT applicants have advised the Medical Services Advisory Committee (MSAC) of a recently started randomised controlled trial that seeks to demonstrate the benefits of HBOT for chronic wounds. The estimated timeframe was 3 years (30 August 2011 to 30 August 2014) .On 16 July 2012 MSAC was informed that the RCT aimed to enrol 64 patients. However, to date, of 37 patients screened, only 8 patients had been enrolled to be randomised in the trial.